UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Jeanne M. Calamore, Derivatively on behalf of JOHNSON & JOHNSON Plaintiff, -against- Mary Sue Coleman, James G. Cullen, Michael M.E. Johns, Arnold G. Langbo, Susan L. Lindquist, Leo F. Mullin, William D. Perez, Charles O. Prince III, David Satcher, William C. Weldon, Christine A. Poon, Steven S. Reinemund, Robert J. Darretta, Ann Dibble Jordan, Henry B. Schacht, James T. Lenehan, Robert N. Wilson, Joseph C. Scodari, Alex Gorsky, Nicholas Valeriani, Russell C. Deyo, Ted Torphy Defendants and JOHNSON & JOHNSON Nominal Defendant.	:	Civil Action No. JURY TRIAL DEMANDED

VERIFIED DERIVATIVE COMPLAINT

I. INTRODUCTION

1. This derivative action arises from systemic and pervasive multi-year breaches of fiduciary duty spanning multiple drugs and medical devices and multiple operating subsidiaries on the part of current and former senior officers and current and former directors of Johnson & Johnson ("J&J" or the "Company") in connection with, *inter alia*, state and federal civil and criminal kickback charges, violations of the federal False Claims Act, the payment of kickbacks, off-label drug promotion, failure to warn and cGMP (current Good Manufacturing Practices) violations in connection with the recall of contaminated over-the-counter ("OTC") products.

2. The allegations against Defendants are based upon personal knowledge as to Plaintiff and her own acts, and on information and belief as to all other matters, such information and belief having been informed by the investigation conducted by and under the supervision of her counsel, which included, among other things: (a) review and analysis of the Company's public filings with the U.S. Securities and Exchange Commission ("SEC"); (b) review of other publicly available information, including press articles; (c) review and analysis of multiple *qui tam* complaints and complaints filed by the Department of Justice and/or state Attorneys General; (d) review of the Company's website; and (e) consultation with Plaintiff's medical and pharmaceutical industry expert. Plaintiff believes that substantial additional evidentiary support will exist for her allegations after a reasonable opportunity for discovery.

II. JURISDICTION AND VENUE

3. This verified shareholder derivative action is brought pursuant to Rule 23.1 of the Federal Rules of Civil Procedure.

4. Plaintiff is a citizen of the United States, domiciled in Connecticut. None of the Defendants is a citizen of Connecticut. The nominal defendant, J&J, is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

5. This Court has diversity jurisdiction over this action pursuant to 28 U.S.C. §1332. The amount in controversy exceeds $75,000, exclusive of interest and costs. This action is not brought collusively to confer jurisdiction on this Court which it would not otherwise have. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(a)(2) and (3) and 1401 because some or all of the events, actions, and failures to act giving rise to the claims asserted herein occurred in this District.

III. THE PARTIES

A. Plaintiff

6. Plaintiff Jeanne M. Calamore ("Plaintiff") owns and has continuously owned common stock in J&J throughout the period of the wrongdoing. The Plaintiff is domiciled in Connecticut.

B. Nominal Defendant

7. Nominal Defendant J&J is a corporation organized under the laws of New Jersey with its principal executive offices and corporate headquarters located in New Brunswick, New Jersey. J&J manufactures and sells pharmaceutical products, medical devices and consumer packaged goods.

8. The Company conducts its operations through multiple subsidiary companies. Contrary to its public representations and claims that "[e]ach of our operating companies functions as its own small business" (J&J website, accessed April 18, 2010), in reality J&J exercises strict supervision, control, and dominion over its subsidiaries activities, decisions,

policies, and practices related to sales goals, sales tactics, compliance, regulatory affairs, medical affairs, research and development, human resources, legal issues, budget, accounting, employee compensation, employee benefits, employee expenses, manufacturing, and public relations. J&J sets the business objectives and sales goals of all its subsidiaries, and regularly reviews and approves their sales numbers and projections.

9. As recognized in a recent academic study focusing on J&J's management behavior, and concluding that J&J routinely reconfigures business units to suit its overall Company objectives, the claim of decentralized management is a myth:

> J&J suits the study particularly well. Indeed, the study may help dispel some myths about the company, that it consists of independent subsidiaries that rely on internal resource creation within the bounds of autonomous organizational business units. By contrast with this view, we demonstrate the vital importance of unit reconfiguration to the company's innovativeness, along with the frequency of obtaining resources via business acquisitions and reconfiguring these resources. Johnson and Johnson continually moved resources within unit boundaries, and updated unit boundaries within the firm, as they pursued innovation.

Samina Karim and Will Mitchell, *Innovating through Acquisition and Internal Development: A Quarter-century of Boundary Evolution at Johnson & Johnson*, "Long Range Planning 37" (2004) 525-547.

10. Accordingly, each subsidiary is in substance the alter ego of the Company, managed through a centralized hierarchical structure, with a management level Executive Committee composed of business segment "Worldwide Chairmen," and corporate senior executive officers exercising plenary control over all Company operations and allocation of Company resources, and under the ultimate authority and oversight of the Board.

C. Current Director Defendants

11. Defendant Mary Sue Coleman, Ph.D. ("Coleman") has been a Director since 2003. Coleman has been a member of the Audit Committee and the Science & Technology Advisory Committee since 2003. Coleman is domiciled in Michigan.

12. Defendant James G. Cullen ("Cullen") has been a Director since 1995, and is the Presiding Director of the Company's Board of Directors (the "Board") and Chairman of the Audit Committee. Cullen has been a member of the Audit Committee since 1997 and a member of the Nominating & Corporate Governance Committee since 2004. Cullen is domiciled in Virginia or New Jersey.

13. Defendant Michael M.E. Johns, M.D. ("Johns") has been a Director since 2005 and is a member of the Compensation & Benefits Committee and the Science & Technology Advisory Committee. Johns is domiciled in Georgia.

14. Defendant Arnold G. Langbo ("Langbo") was elected to the Board in 1991 and is a member of the Nominating & Corporate Governance Committee and Chairman of the Compensation and Benefits Committee. In addition, Langbo served on the Audit Committee from 1997 through 2003. Langbo has been a member of the Nominating & Corporate Governance Committee since 2004. Langbo is domiciled in Vermont.

15. Defendant Susan L. Lindquist, Ph.D. ("Lindquist") was elected to the Board in 2004 and is a member of the Science & Technology Advisory Committee and the Public Policy Advisory Committee. Lindquist has been a member of the Public Policy Advisor Committee and the Science & Technology Advisory Committee since 2004. Lindquist is domiciled in Massachusetts.

16. Defendant Leo F. Mullin ("Mullin") has been a Director since 1999 and is a member of the Audit Committee and Chairman of the Public Policy Advisory Committee. Mullin has been a member of the Audit Committee since 2000, a member of the Public Policy Advisory Committee since 2006 and a member of the Nominating & Corporate Governance Committee from 2000 to 2005. Mullin is domiciled in Georgia.

17. Defendant William D. Perez ("Perez") was elected to the Board in 2007 and is a member of the Compensation & Benefits Committee and the Public Policy Advisory Committee. Perez has been a member of the Public Policy Advisory Committee since 2008. Perez is domiciled in Oregon.

18. Defendant Charles O. Prince III ("Prince") was elected to the Board in 2006 and is a member of the Compensation & Benefits Committee and chairman of the Nominating & Corporate Governance Committee. Prince has been a member of the Nominating & Corporate Governance Committee since 2007. Prince is domiciled in New York or Florida.

19. Defendant David Satcher, M.D., Ph.D. ("Satcher) was elected to the Board in 2002 and is Chairman of the Science & Technology Advisory Committee and a member of the Public Policy Advisory Committee. Satcher has been a member of the Public Policy Advisory Committee and of the Science & Technology Advisory Committee since 2003. Satcher is domiciled in Georgia.

20. Defendant William C. Weldon ("Weldon") was elected to the Board and named Vice Chairman of the Board in 2001 and assumed his current responsibilities as Chairman of the Board and Chief Executive Officer, in April 2002. He was appointed to the Executive Committee and named Worldwide Chairman, Pharmaceuticals Group, in 1998, and became Chairman of the Executive Committee in 2002. Weldon joined the Company in 1971 as a sales

representative at McNeil Pharmaceutical. In 1989, he became Vice President, Sales and Marketing for Janssen Pharmaceutical. In 1992, he became president of Ethicon Endo-surgery, and in this position gained experience in medical devices, serving as Company Group Chairman and worldwide Franchise chairman for EthiconEndo-Surgery from 1995 through 1998. He was named Worldwide Chairman, Pharmaceuticals Group, in 1998. Weldon is domiciled in Pennsylvania.

D. Former Director Defendants

21. Defendant Christine A. Poon ("Poon") was elected to the Board and named a Vice Chairman of the Board in 2005. She left the Board on March 1, 2009. Her career with J&J began in November, 2000, as Company Group Chairman, Pharmaceuticals. In August, 2001, she was promoted to the Executive Committee and named Worldwide Chairman, Pharmaceuticals. In October, 2003, she was appointed Worldwide Chairman, Medicines and Nutritionals. In 2007, Poon assumed responsibility for the J&J Development Corporation, the Corporate Office of Science and Technology, the Corporate Office of Information Management, Worldwide Procurement and Worldwide Operations. Poon is domiciled in Ohio.

22. Defendant Steven S. Reinemund ("Reinemund") was elected to the Board in 2003 and left the Board on April 24, 2008. While on the Board, he was a member of the Nominating & Corporate Governance Committee from 2004 to 2008. Reinemund is domiciled in North Carolina.

23. Defendant Robert J. Darretta ("Darretta") was elected to the Board in 2002 and served on the Board until 2006. Mr. Darretta was named Vice President, Finance and Chief Financial Officer and appointed to the Executive Committee in 1997. He was appointed

Executive Vice President in 2002 and Vice Chairman of the Board in January 2004. Darretta is domiciled in New Jersey.

24. Defendant Ann Dibble Jordan ("Jordan") served on the Board from 1981 to 2007. She served on the Compensation & Benefits Committee and the Audit Committee, and was Chairman of the Public Policy Advisory Committee. Jordan is domiciled in Washington, D.C.

25. Defendant Henry B. Schacht ("Schacht") was a Director of Johnson & Johnson from 1997 to April 28, 2005 and served as a Member of the Audit Committee and the Chairman of the Nominating and Corporate Governance Committees. Schacht is domiciled in New York.

26. Defendant James T. Lenehan ("Lenehan") served on the Board from 2001 until February 1, 2004. Lenehan started his career in 1976 at McNeil Consumer Products Company and became McNeil's President in 1990. In 1993, Lenehan was named Company Group Chairman and worldwide Franchise Chairman for Consumer Pharmaceuticals and a member of the Consumer Group Operating Committee. In 1994, he was promoted to Executive Committee member and Worldwide Chairman, Consumer Pharmaceuticals & Medical Devices Group. He was Worldwide Chairman of Johnson & Johnson's Medical Devices and Diagnostics Group from 1999 to 2001, when he became Vice Chairman of the Board, a position in which he also had responsibility for the consumer business. He was named to the additional position of President of Johnson & Johnson in 2002, a position he held until February, 2004. Lenehan is domiciled in Pennsylvania.

27. Defendant Robert N. Wilson ("Wilson") was elected to the Board in 1986 and resigned in April, 2003. He served as Vice Chairman of the Board from 1989 until 2002. He joined the Company in 1964, served in several sales and marketing management positions and was appointed Company Group Chairman in 1981. Wilson was appointed to the Executive

Committee in 1983. He was appointed Chairman of a Sector Operating Committee in 1985, was appointed Vice Chairman of the Board of Directors in 1989. He was named Senior Vice Chairman of the Board of Directors in 2001. He assumed expanded responsibilities as Vice Chairman of the Executive Committee in 1994. Wilson also served on the Science and Technology Advisory Committee. Wilson is domiciled in New Jersey.

E. Officer Defendants

28. In addition to being named as Current or Former Director Defendants above, Defendants Weldon, Poon, Lenehan, Daretta and Wilson are also named as Officer Defendants.

29. Defendant Joseph C. Scodari ("Scodari") joined J&J in 1999 as President and Chief Operating Officer of Centocor, Inc., when J&J acquired the company and in 2001 he was named Company Group Chairman for the Johnson & Johnson North American Pharmaceuticals business, and became a member of the Pharmaceuticals Group Operating Committee. From 2003 to 2005, Mr. Scodari was Company Group Chairman of J&J's Biopharmaceutical Business, and was Worldwide Chairman, Pharmaceuticals Group, and a member of the Executive Committee from March 2005 until March, 2008. Scodari is domiciled in Pennsylvania.

30. Defendant Alex Gorsky ("Gorsky") is Worldwide Chairman, Medical Devices and Diagnostics Group since September 2009, and a member of Johnson & Johnson's Executive Committee since January 2009. He joined Johnson & Johnson in 2008 as Company Group Chairman and Worldwide Franchise Chairman for Ethicon, Inc. Previously, he was head of the North American pharmaceuticals business at Novartis Pharmaceuticals Corporation from 2004 to 2008. Prior to 2004, Mr. Gorsky served in various management positions at Johnson & Johnson, beginning as a sales representative with Janssen Pharmaceutica Inc in 1988. Over the next 15 years, he advanced through positions of increasing responsibility in sales, marketing and

management, and was named President of Janssen Pharmaceutica Inc. in the U.S. in 2001. His responsibilities included the commercial development of Risperdal (risperidone), Duragesic/ Durogesic (fentanyl transdermal system), Aciphex/Pariet (rabeprazole sodium) and Reminyl/ Razdyne (galantamine HBr). In 2003, Gorsky was promoted to company group chairman for the Johnson & Johnson Family of Companies pharmaceutical business in Europe, the Middle East and Africa. Gorsky is domiciled in Pennsylvania.

31. Defendant Nicholas Valeriani ("Valeriani") is Vice President, Strategy & Growth, a position he has held since February, 2007. Valeriani has been with the J&J family of companies since 1978. In 1996, he was named General Manager of Indigo Medical, Inc. and he became President of Ethicon Endo-Surgery, Inc. in 1997. In January, 2001, he was named Company Group Chairman with responsibility for Ethicon Endo-Surgery, Inc., and the Johnson & Johnson Medical Products Canadian Medical Device & Diagnostic business. The following year he became Worldwide Franchise Chairman for the DePuy franchise. He was promoted to Corporate Vice President, Human Resources, Johnson & Johnson, and became a member of the Executive Committee in September 2003, with responsibility for worldwide management succession and organization development, compensation and benefits, education and training, recruiting, equal opportunity, affirmative action, human resources policies, and employee and labor relations. Mr. Valeriani also chaired the Corporate Contributions Committee and was a member of the Management Compensation Committee and the Pension Committee. Additionally, in the first quarter of 2004, he assumed responsibility for the Company's diagnostics businesses and was named Worldwide Chairman, Diagnostics. In 2004, Valeriani was named Worldwide Chairman, Cardiovascular Devices and Diagnostics. In 2006, he assumed responsibility for a newly-created Cardiovascular Devices & Diagnostics Group

Operating Committee, which included LifeScan, Inc., Cordis Corporation and Ortho-Clinical Diagnostics, Inc. Valeriani is domiciled in New Jersey.

32. Russell C. Deyo ("Deyo") joined the Company in 1985 and became Associate General Counsel in 1991. He became a member of the Executive Committee and Vice President, Administration in 1996 and Vice President, General Counsel and Chief Compliance Officer in April, 2004. Deyo was given the additional responsibility for Human Resources in November, 2009. Mr. Deyo has responsibility for the legal affairs and legal compliance activities of Johnson & Johnson and its operating subsidiaries, and also has responsibility for the Office of Corporate Secretary, Government Affairs and Policy, and the Corporate Health Care Compliance, Privacy, Security and Aviation Departments. He is on the Public Policy Advisory Committee of the Board. Deyo is domiciled in New Jersey.

33. Defendant Ted Torphy ("Torphy") was Corporate Vice President, Office of Science and Technology at J&J until 2006. Torphy joined J&J's corporate staff in 2003 as Corporate Vice President for Science and Technology, after three years at J&J's Centacor subsidiary, where he was Senior Vice President for Discovery and Preclinical Development. Prior to joining Centacor, Torphy spent seventeen years with SmithKline Beecham, most recently as Vice President of Research for Cardiovascular, Pulmonary and Metabolic Diseases therapeutic areas. As reported in the Company's Annual Reports, Torphy acted as the officer representative on the Board's Science & Technology Advisory Committee from 2003 through 2006.

IV. SUBSTANTIVE ALLEGATIONS

A. The Omnicare Kickback Scheme

34. In its November 7, 2005 Form 10-Q, J&J first disclosed that on September 26, 2005, the Company had received a subpoena from the United States Attorney's Office, District of Massachusetts, seeking documents related to sales and marketing of eight drugs to Omnicare, Inc., a manager of pharmaceutical benefits for long-term care facilities.

35. On January 15, 2010, the United States Department of Justice announced that it had filed a civil False Claims Act complaint (the "Federal Kickback Complaint") against J&J and two of its subsidiaries, Ortho-McNeil-Janssen Pharmaceuticals Inc. and Johnson & Johnson Health Care Systems Inc. The Federal Kickback Complaint and all exhibits thereto are attached as Exhibits 1 through 4 hereto, and incorporated by reference herein.

36. The Federal Kickback Complaint alleges that the Company and its subsidiaries, in violation of the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), paid millions of dollars in kickbacks to Omnicare Inc., ("Omnicare") thereby causing Omnicare, the nation's largest long-term care pharmacy, to submit false claims to Medicaid during the period from 1999 through 2004 (the "Omnicare Kickback Scheme").

37. The federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that remuneration given to those who can influence healthcare decisions would result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of the Medicare and Medicaid programs from these harms, Congress enacted a prohibition against the payment of kickbacks in any form.

38. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. See Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93. 12. The anti-kickback statute prohibits any person or entity from knowingly and willfully offering, making, soliciting, or accepting remuneration, in cash or in kind, directly or indirectly, to induce or reward any person for purchasing, ordering, or recommending or arranging for the purchasing or ordering of federally-reimbursable medical goods or services:

> [W]hoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person –
>
> > (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> >
> > (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b)(2). Violation of the statute also can subject the perpetrator to exclusion from participation in federal health care programs and, effective August 6, 1997, civil monetary penalties of $50,000 per violation and three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

39. During the period 1999 through 2004, Omnicare was one of J&J's largest customers, especially for Risperdal, a J&J antipsychotic drug that, at J&J's behest, Omnicare pharmacists recommended for nursing home patients who exhibited behavioral symptoms

associated with Alzheimer's Disease and dementia. Over the period 1999 through 2004, under the Omnicare Kickback Scheme, J&J paid Omnicare tens of millions of dollars in kickbacks pursuant to two separate, consecutive drug supply agreements, one entered into in 1997 and the second entered into in 2004.

40. Pursuant to the scheme, as set forth in the Federal Kickback Complaint, during the five year period of 1999 through 2004, J&J, including through the named subsidiaries, paid Omnicare tens of millions of dollars in the form of illegal kickbacks to induce Omnicare to purchase and recommend Risperdal and other J&J drugs. These payments caused Omnicare to submit false reimbursement claims to Medicaid.

41. J&J targeted Omnicare in this scheme because, through contracts with nursing homes, it dispenses drugs to approximately 1.4 million long-term care residents in 47 states. Omnicare also provides consultant pharmacist services to nursing homes. As known to J&J, Omnicare's pharmacists and consultant pharmacists have significant influence over the drugs that nursing home residents receive.

42. J&J paid the kickbacks involved under the Omnicare Kickback Scheme in numerous ways. For example, J&J entered into agreements with Omnicare by which Omnicare was entitled to receive increasing levels of rebates from the Company so long as Omnicare implemented specific programs to increase the sales of J&J drugs.

43. J&J and its employees understood that it was a violation of the anti-kickback statute to offer or to pay remuneration, by whatever means, to induce a customer like Omnicare to purchase or to recommend J&J drugs. For example, J&J understood from its outside counsel that the company could violate the law through market share rebate agreements, *i.e.*, agreements where J&J agreed to pay customers rebates for switching patients from competitors' drugs to J&J

drugs. (A copy of an internal J&J e-mail chain reflecting this understanding is attached to the Federal Kickback Complaint as Exhibit 7.) J&J employees also understood that it would be a kickback to pay a customer like Omnicare for the sake of fostering a relationship or for good will, where J&J's goal was always to convince Omnicare to purchase and to recommend J&J drugs.

44. As the Federal Kickback Complaint alleges, notwithstanding J&J's understanding of the anti-kickback statute, J&J repeatedly violated the statute in its relationship with Omnicare by paying Omnicare rebates to switch patients to J&J drugs, and paying Omnicare various grants and sponsorship fees whose purpose was to induce Omnicare to purchase and to recommend J&J drugs. Notably, J&J recognized the problematic nature of its relationship with Omnicare. As one J&J employee described in a September 2002 internal meeting, J&J's Omnicare sales team "got hammered re Healthcare Compliance." (A copy of the e-mail containing this statement is attached to the Federal Kickback Complaint as Exhibit 9.) Nevertheless, J&J continued to pay the Omnicare kickbacks until 2004.

45. In addition, J&J also paid Omnicare millions of dollars for "data," much of which J&J never required to be submitted, and Omnicare never provided, or that Omnicare had already historically been providing free of charge. J&J first discussed this "data purchase" scheme in 1999 and then implemented it beginning in 2000 as a method to avoid triggering Medicaid Best Price reporting requirements for Risperdal by replacing direct pricing rebates with ostensibly unrelated payments to Omnicare. This subterfuge was implemented through Consulting and Services Agreement entered into in October 2000. The agreement had a term of July 1, 2000 to April 2004, and called for J&J to pay Omnicare $450,000 for the first three-month period of the term, and then $300,000 per quarter thereafter, for a total of $4,650,000. At exactly the same

time J&J and Omnicare signed the Consulting and Services Agreement, they eliminated certain Risperdal pricing rebates from their overall agreement.

46. The Consulting and Services Agreement was designed and implemented despite J&J's knowledge and explicit recognition that it constituted illegal fraud and abuse under federal law. In connection with a dispute over rebates Omnicare claimed it was owed for an earlier period (from the second quarter of 1997 to the first quarter of 1998), J&J had concluded in June 1999 that paying for data in lieu of the rebate claimed by Omnicare would "put us at risk for fraud and abuse." (A copy of the J&J e-mail chain containing this statement is attached to the Federal Kickback Complaint as Exhibit 23.)

47. The data payments under the Consulting and Services Agreement were made in the face of J&J's standing policy against paying for data. For example, a J&J Director of National Accounts publicly stated: J&J Pharma, has previously gone on record, from corporate, that . . . [w]e will *not* pay customers for data." (Emphasis in Federal Kickback Complaint, ¶34.)

48. Even though Omnicare did not provide the data it was contractually obligated to provide in the Consulting and Services Agreement, J&J paid Omnicare as specified under the Agreement. In cover letters enclosing J&J's payments to Omnicare pursuant to the Consulting and Services Agreement, J&J referred to each payment as a "marketing fee." The letters also cautioned Omnicare that "some or all of this amount may be considered a Discount which Omnicare may have an obligation to reflect in any cost report or claim for reimbursement with Medicare/Medicaid," even though, as alleged in the Federal Kickback Complaint, J&J itself did not treat the payments as discounts and did not disclose them to Medicaid.

49. J&J also made various other substantial kickback payments to Omnicare, attempting to disguise such kickback payments by describing them as "grants" and "educational

funding," even though their true purpose was to provide improper and illegal financial incentives in order to induce Omnicare to recommend J&J's products. The Federal Kickback Complaint states that in January 1999, J&J noted that it had paid Omnicare "in excess of $1,000,000 since 1997 for educational, pull-through, and social activities." J&J continued to make such payments in subsequent years as well.

50. The Department of Justice ("DOJ") press release announcing the filing of the Federal Kickback Complaint characterized the Omnicare kickback's as an illegal scheme to "take advantage of the elderly and the poor." The DOJ charges in the Federal Kickback Complaint that J&J viewed Omnicare's pharmacists as "an extension of [J&J's] sales force."

51. J&J tracked and monitored its financial return from rebates it provided to Omnicare. For example, in 2003, J&J determined that, "for a $3MM investment in rebates with Omnicare, [J&J] gains $9MM in sales, less costs and investments, returns $4.8 MM to OMP." Another J&J manager calculated that J&J could generate the same return with just $1.44 million in rebates. J&J further understood that "Rebates represent approximately 60%+ of [Omnicare's] net income model."

52. Pursuant to the illegal Omnicare kickback Scheme, J&J was able to increase sales of Risperdal and other J&J drugs to geriatric patients in long-term care facilities. In return for the kickbacks J&J paid, during the 1999 through 2004 period, Omnicare undertook and engaged in intensive efforts to convince physicians to prescribe J&J drugs. In addition, Omnicare's own annual purchases of J&J drugs increased from approximately $100 million to over $280 million, with annual purchases of Risperdal, alone, increasing to over $100 million.

53. As demonstrated by dozens of internal J&J documents attached as exhibits to the Federal Kickback Complaint, and incorporated herein, the scheme was a deliberate, coordinated, long-term effort to increase J&J drug sales to these patients through illegal means.

54. The DOJ is seeking to recover unspecified treble damages, restitution and civil penalties against J&J and its named subsidiaries based on the false claims submitted to Medicaid by Omnicare as a result of the kickback scheme. Reflecting the potential magnitude of the civil liability J&J faces on these claims, separately, in November 2009, the United States, numerous states, and Omnicare entered into a $98 million settlement agreement that, among other things, resolved Omnicare's civil liability under the False Claims Act for taking kickbacks from J&J.

55. Based on the magnitude of the Omnicare settlement, and the size and profitability to J&J from its increased annual sales of its drugs to Omnicare over the period of 1999 through 2004 resulting from its illegal conduct, and J&J's deliberate structuring of discounted pricing for Risperdal as a phony "data purchase" contract in order to avoid Medicaid Best Price reporting requirements, J&J faces potential liability in the hundreds of millions of dollars.

56. J&J, via its subsidiary, then known as Janssen Research Foundation, received an FDA Warning Letter dated January 5, 1999 in connection with the Company's off-label promotion of Risperdal to geriatric patients. Internal J&J documents demonstrate that the Omnicare kickback scheme represented a deliberate effort to promote Risperdal for off-label treatment of dementia in geriatric patients residing in long-term care facilities. For example, according to an internal J&J memorandum from the summer of 2000, Omnicare's ongoing Risperdal Initiative "has generated an all time market share high of 55.5% throughout the 1st quarter of 2000. This market share represents Omnicare's ability to persuade physicians to write Risperdal in the areas of Behavioral Disturbances associated with Dementia."

57. The Omnicare Kickback Scheme itself represents one aspect of J&J's multi-billion dollar exposure to liability for unlawful off-label promotion of Risperdal, Natrecor, and Topamax, which are each the subject of separate federal investigations, described below.

58. The Omnicare Kickback Scheme addressed by the Federal Kickback Complaint has caused, and will continue to cause, financial harm to the Company, including, *inter alia*, the costs of responding to governmental investigations and defending related legal proceedings, fines, penalties or settlement payments in connection with the federal action and related enforcement actions, and harm to J&J's reputation and goodwill.

B. Illegal Off-Label Promotion of Risperdal, Natrecor and Topamax

59. J&J reported in its March 2007 Annual Report that the Company has received separate subpoenas from the U.S. Attorney's Office in Philadelphia, the U.S. Attorney's Office in Boston and the U.S. Attorney's Office in San Francisco. These subpoenas relate to investigations by these three offices regarding, respectively, sales and marketing of Risperdal, Topamax, and Natrecor by J&J through certain named subsidiaries. According to the Annual Report, the subpoenas request information regarding the Company's corporate supervision and oversight of three Company subsidiaries, including their sales and marketing of these identified drugs.

60. To put the critical importance of these drugs into perspective at J&J, for example, in 2004, the Pharmaceuticals Segment at the Company was responsible for generating 46.7% of total Company revenues ($22.128 billion of a total of $47.348 billion). Of that amount, the blockbuster drugs Risperdal and Topamax, together, were responsible for approximately 20% of the segment's revenues; in 2005, they were responsible for approximately 23.4% of the segment's total revenues of $22.322 billion; in 2006, they were responsible for approximately

26.7% of the segment's total revenues of $23.267 billion; in 2007, they were responsible for approximately 28.7% of the segment's total revenues of $24.866 billion; and in 2008, in light of Risperdal's patent expiration in June 2008, these drugs were responsible for approximately 20.1% of the segment's total revenues of $24.567 billion.

61. The U.S. Attorney's Office in Boston has also, separately issued subpoenas to employees of Johnson & Johnson requiring their testimony before a grand jury. The March 2007 subpoenas reflect an apparent coordinated investigation by the United States Justice Department of the off-label promotion of J&J drugs. In light of recent federal and state investigations, enforcement actions, and settlements involving off-label promotion of prescription drugs, the Company faces likely liability exposure in the amount of multiple billions of dollars as the result of deliberate and knowingly unlawful off-label promotion of Risperdal, Topamax, and Natrecor. For example, sales of Risperdal alone between 1994 and 2008 were approximately $29 billion, with approximately 60% of that amount attributable to off-label sales. Based on recent settlements involving other atypical antipsychotics such as Zyprexa, Abilify and Gedeon, J&J's liability exposure with respect to Risperdal alone exceeds $1 billion.

62. To understand what off-label promotion and marketing entails, the Federal Food, Drug, and Cosmetic Act ("FDCA") requires that the manufacturer or sponsor of a new drug submit a New Drug Application ("NDA") to the Food and Drug Administration ("FDA"), which identifies all of the proposed uses of the drug intended by the manufacturer, together with the proposed label for those uses, as well as data generated in randomized, adequate and well-controlled clinical trials. Approval requires that the data demonstrate to the FDA's satisfaction that the drug will be safe and effective for its intended uses. *See* 21 U.S.C. §331(d) and §355(b).

63. In order for the FDA to approve a drug, the manufacturer must demonstrate that the drug is "safe for use" for all "conditions prescribed, recommended, or suggested" in the drug's label. 21 U.S.C. §355(b). Until the FDA approves the NDA, including the proposed labeling, and makes a determination regarding safety and efficacy for the uses proposed, the FDCA prohibits the manufacturer from introducing the drug into interstate commerce. 21 U.S.C. §355(a).

64. After the FDA approves the NDA, the sponsor is permitted to promote and market the drug, but only for the medical conditions or uses specified in the approved labeling. The term "off-label promotion" or "off-label uses" refers to any promotion of the drug for uses not approved by the FDA and included in the drug's approved label. While physicians are free to prescribe the drug for whatever conditions they see fit, the FDA prohibits drug companies from promoting off-label uses to doctors. A manufacturer may not legally label or promote the drug for any new use without prior FDA approval.

1. The Risperdal Off-Label Promotion Scheme

65. In its March 11, 2004 Annual Report for the year ended December 31, 2003, issued on March 11, 2004 and signed by Defendants Weldon, Darretta, Cullen, Coleman, Jordan, Langbo, Lindquist, Mullin, Reinemund, Satcher, and Schacht, J&J first reported that:

> In January 2004, Janssen (now OMJPI) received a subpoena from the Office of the Inspector General of the U.S. Office of Personnel Management seeking documents concerning sales and marketing of, any and all payments to physicians in connection with sales and marketing of, and clinical trials for, RISPERDAL® (risperidone) from 1997 to 2002.

66. J&J continued to receive subpoenas or requests for information relating to the sales and marketing of Risperdal after the 2004 subpoena, all of which were known to the Board. The Annual Report for the fiscal year ended January 2, 2005, filed March 15, 2005, and signed

by Defendants Weldon, Darretta, Coleman, Cullen, Jordan, Langbo, Lindquist, Mullin, Reinemund, Satcher, and Schacht, reported on a request from the New York State Attorney General's Office for documents pertaining to marketing, off-label sales and clinical trials for Risperdal (as well as Topomax, Procrit (Epoetin alfa), Reminyl (galantamine HBr), Remicade (infliximab) and Aciphex (rabeprazole sodium).

67. The Annual Report for fiscal year ended January 1, 2006, filed March 14, 2006 and signed by Defendants Weldon, Darretta, Poon, Coleman, Cullen, Johns, Jordan, Langbo, Lindquist, Mullin, Prince, Reinemund, and Satcher, reported on, *inter alia*: (i) the investigation by the U.S. Attorney's Office for the Eastern District of Pennsylvania regarding the marketing of and adverse reactions to Risperdal; (ii) subpoenas of Company employees to appear before a grand jury; and (iii) a civil investigative demand from the Texas Attorney General seeking broad categories of documents related to sales and marketing of Risperdal.

68. The Annual Report for the fiscal year ended December 31, 2006, filed on February 21, 2007 and signed by Defendants Weldon, Darretta, Poon, Coleman, Cullen, Johns, Jordan, Langbo, Lindquist, Mullin, Prince, Reinemund and Satcher, reported on the subpoena from the California Attorney General seeking documents regarding sales and marketing and side-effects of RISPERDAL, as well as interactions with State officials regarding the State's formulary for Medicaid-reimbursed drugs.

69. The Annual Report for the fiscal year ended December 30, 2007, filed on February 26, 2008 and signed by Defendants Weldon, Poon, Coleman, Cullen, Johns, Langbo, Lindquist, Mullin, Perez, Prince, Reinemund and Satcher, reported on, *inter alia*: (i) the subpoena from the U.S. Attorney's Office in Philadelphia concerning both Janssen's sales and marketing of RISPERDAL and J&J's supervision and oversight of Janssen; and (ii) the request

from Senator Grassley on behalf of the Committee on Finance of the U.S. Senate for documents and information concerning the marketing and promotion of RISPERDAL for use by nursing home patients; (iii) the filing of the State Risperdal Complaints; and (iv) the filing of six cases filed by union health plans seeking damages for alleged overpayments for RISPERDAL.

70. As referenced above, beginning in with its Annual Report for the fiscal year ending December 31, 2007, the Company disclosed that several states have commenced actions (the "State Risperdal Complaints") seeking to recover damages and other relief for harm caused by the off-label promotion of Risperdal (the "Risperdal Off-Label Promotion Scheme"). Copies of State Risperdal Complaints filed on behalf of the States of Arkansas, Louisiana, South Carolina and Texas, and the Commonwealth of Pennsylvania are attached hereto as Exhibits 5 through 9 hereto, respectively, and are incorporated by reference herein.

71. The Company provided a more detailed history of governmental investigations of alleged Risperdal off-label promotion in its most current Annual Report filed with the SEC on March 1, 2010 for the year ended December 31, 2010:

> In January 2004, Janssen (now OMJPI) received a subpoena from the Office of the Inspector General of the U.S. Office of Personnel Management seeking documents concerning sales and marketing of, any and all payments to physicians in connection with sales and marketing of, and clinical trials for, RISPERDAL® (risperidone) from 1997 to 2002. Documents subsequent to 2002 have also been requested. An additional subpoena seeking information about marketing of and adverse reactions to RISPERDAL® was received from the U.S. Attorney's Office for the Eastern District of Pennsylvania in November 2005. Subpoenas seeking testimony from various witnesses before a grand jury have also been received. Janssen is cooperating in responding to ongoing requests for documents and witnesses. The government is continuing to actively investigate this matter. In February 2010, the government served Civil Investigative Demands seeking additional information relating to sales and marketing of RISPERDAL® and sales and marketing of INVEGA®.

72. The Annual Report goes on to state:

> With respect to RISPERDAL ®, the Attorneys General of eight states and the Office of General Counsel of the Commonwealth of Pennsylvania have filed actions seeking reimbursement of Medicaid or other public funds for RISPERDAL® prescriptions written for off-label use, compensation for treating their citizens for alleged adverse reactions to RISPERDAL®, civil fines or penalties, punitive damages, or other relief. The Attorney General of Texas has joined a qui tam action in that state seeking similar relief. Certain of these actions also seek injunctive relief relating to the promotion of RISPERDAL®. The Attorneys General of more than 40 other states have indicated a potential interest in pursuing similar litigation against the Company's subsidiary, Janssen Pharmaceutica Inc. (Janssen) (now Ortho-McNeil-Janssen Pharmaceuticals Inc. (OMJPI)), and have obtained a tolling agreement staying the running of the statute of limitations while they inquire into the issues. In addition, there are six cases filed by union health plans seeking damages for alleged overpayments for RISPERDAL®, several of which seek certification as class actions. In the case brought by the Attorney General of West Virginia, based on claims for alleged consumer fraud as to DURAGESIC® as well as RISPERDAL®, Janssen (now OMJPI) was found liable and damages were assessed at $4.5 million.

73. In late 1993, Risperdal became the second atypical antipsychotic to receive FDA approval. Before 1993, the only atypical antipsychotic in the United States market was clozapine; however, the potential of clozapine to cause toxic side effects, including agranulocytosis, limited its prescription to a small percentage of the patient market. According to the State Risperdal Complaints, J&J, through its Janssen subsidiary, obtained the first United States marketing approval of Risperdal from the FDA in late 1993, and commenced aggressive marketing of the drug in 1994. From the outset, J&J actively promoted Risperdal not only for its approved indication, but also for numerous off-label uses, including ADHD, depression, anxiety, mood disorder, bipolar disorder, and aggression associated with late-onset dementia. By late 1996, Defendants had significant market share for United States antipsychotic drug use, and had demonstrated to the pharmaceutical manufacturing industry the tremendous sales potential of marketing atypical antipsychotic drugs for off-label use.

74. J&J had recognized the commercial potential of promoting Risperdal for off-label uses from the outset. According to a March 10, 2010 article published by *Bloomberg.com*, Ivo Caers, a Janssen executive, wrote in a 1994 report that "Schizophrenia represents only 35 percent" of antipsychotic prescriptions, ... Aggressive expansion of Risperdal use in other indications is therefore mandatory."

75. Pursuant to the Risperdal Off-Label Promotion Scheme, J&J commenced a deliberate and multi-faceted off-label promotion campaign for the drug, which included, *inter alia*: (i) inducements to "key opinion leaders" to publicly disseminate information concerning off-label uses of Risperdal; (ii) control over the content of Continuing Medical Education ("CME") programs in which presenters would disseminate information concerning off-label uses of Risperdal; (iii) initiating, controlling, and producing scientifically-insignificant studies (small-scale clinical trials, investigator-initiated research, and pilot studies) not for the purpose of legitimate scientific research, but instead to spread information concerning off-label uses of Risperdal; (iv) causing the publication of "ghost written" articles – written by J&J-paid personnel but signed by ostensibly independent doctors and researchers – promoting off-label uses of Risperdal; (v) promoting the development of Medication Algorithms utilized by states to prioritize medications to be used for specific conditions, which algorithms specifically included the use of Risperdal in unapproved indications.

76. As a result of the Risperdal Off-Label Promotion Scheme, annual sales of the drug skyrocketed from zero on January 1, 1994 to over $3.4 billion in 2005, with Risperdal becoming the most widely used atypical antipsychotic in the world.

77. On November 24, 2008, *The New York Times* reported on one example of off-label promotion and marketing tactics applied by J&J to drive Risperdal sales – the Company's

funding, beginning in 2002, of a research center for child psychopathology at Massachusetts General Hospital, run by Dr. Joseph Biederman, "to move forward the commercial goals of J&J." According to the article, "Dr. Biederman's work helped to fuel a fortyfold increase from 1994 to 2003 in the diagnosis of pediatric bipolar disorder and a rapid rise in the use of powerful, risky and expensive antipsychotic medicines in children."

78. Internal J&J emails from 2002 indicate that the Company's sales and marketing organization was intimately involved in the discussions that led to J&J's funding of the center. For example, a February 2002 e-mail message from Georges Gharabawi, a J&J executive, stated that Dr. Biederman approached the Company "multiple times to propose the creation" of the center. "The rationale of this center," the message stated, "is to generate and disseminate data supporting the use of [Risperdal] in" children and adolescents. At that time, Risperdal was not approved by the FDA for use in children and adolescents.

79. J&J's support for Dr. Biederman's work was not limited to funding. *The New York Times* further reported that internal J&J "documents also show that the company prepared a draft summary of a study that Dr. Biederman, of Harvard, was said to have written." According to the article:

> A June 2002 e-mail message to Dr. Biederman from Dr. Gahan Pandina, a Johnson & Johnson executive, included a brief abstract of a study of Risperdal in children with disruptive behavior disorder. The message said the study was intended to be presented at the 2002 annual meeting of the American Academy of Child and Adolescent Psychiatry.
>
> "We have generated a review abstract," Dr. Pandina wrote, "but I must review this longer abstract before passing this along."
>
> One problem with the study, Dr. Pandina wrote, is that the children given placebos and those given Risperdal both improved significantly. "So, if you could," Dr. Pandina added, "please give some thought to how to handle this issue if it occurs."

> The draft abstract that Dr. Pandina put in the e-mail message, however, stated that only the children given Risperdal improved, while those given placebos did not. Dr. Pandina asked Dr. Biederman to sign a form listing himself as the author so the company could present the study to the conference, according to the message.

80. As reported in the article, not only did J&J deliberately act to stimulate demand for off-label uses of Risperdal in children by funding and ghost writing for Dr. Biederman, it also paid him to make misleading presentations concerning the results of clinical studies.

81. The March 10, 2010 *Bloomberg.com* article further reports that J&J, through its Janssen subsidiary:

> sought to sell Risperdal for bipolar disorder, dementia, mood and anxiety disorders and other unapproved uses, the documents show. Sales exceeded Janssen's expectations, according to the plans. Though Janssen predicted in 1993 it would take seven years to reach $295 million, U.S. sales hit $343 million in 1995.
>
> Hundreds of Janssen salespeople sold to doctors, nursing homes, Veteran's Administration facilities and jails, the records show. Marketers gave doctors materials about studies of unapproved uses for Risperdal. Janssen sponsored clinical trials of the drug's effect on other illnesses.
>
> In 1994, 1999 and 2004, the FDA ordered Janssen to stop making false and misleading marketing claims about Risperdal's superiority.
>
> Janssen set sales goals for 2000 of $302 million for geriatric sales, or 57 percent of the market, and $175 million in bipolar sales, or 32 percent, according to the business plan. That same year, Janssen planned to expand its geriatric sales force by 50 to 136 people, according to the business plan.
>
> It wasn't until 2003 that the FDA approved Risperdal for bipolar disorder. In 2006, the regulator approved it for symptoms related to autism in children and teens. The FDA approved it to treat bipolar children and teens the next year.
>
> The drug was never approved for dementia.

82. As discussed above, the Omnicare Kickback Scheme also reflected J&J's efforts to promote Risperdal for off-label uses. Specifically, under the Omnicare Kickback Scheme,

J&J rewarded Omnicare for its ability to promote the use of Risperdal for elderly patients suffering from dementia – an off-label use of the drug not approved by the FDA. J&J aggressively pursued this scheme in the face of the January 5, 1999 FDA Warning Letter concerning the off-label promotion of Risperdal to geriatric patients. The *Bloomberg.com* article goes on to report:

> Johnson & Johnson made plans to reach $302 million in geriatric sales for its antipsychotic Risperdal just months after federal regulators said the company falsely claimed the drug was safe and effective with the elderly, according to internal documents.
>
> The U.S. Food and Drug Administration told J&J in 1999 that its marketing materials for geriatric patients overstated Risperdal's benefits and minimized risks. A J&J business plan for the next year called for increasing the drug's market share for elderly dementia sales, an unapproved use, according to newly unsealed documents in a lawsuit by the state of Louisiana.
>
> "The geriatric market represents Risperdal's second wave of growth," J&J officials wrote in the business plan. "The aging population will continue to drive market growth well into the next century."
>
> Louisiana officials cited the document and dozens of other internal J&J files in its lawsuit claiming the company marketed Risperdal to the elderly and children for unapproved uses. Professor Jerry Avorn of Harvard Medical School, who isn't involved in the case, called the papers "one of the more egregious examples" of marketing drugs to vulnerable patients.

83. The State Risperdal Complaints also allege that while deliberately promoting Risperdal for off-label uses in children and the elderly, J&J acted to downplay the known health risks of Risperdal to patients, and made scientifically unsubstantiated claims regarding the safety of Risperdal, as compared to competing atypical antipsychotic drugs. As a result, the Company faces substantial liability for the failure to warn patients treated with Risperdal of known health risks associated with its use, including. but not limited to risks of tardive dyskinesia; increased risk of stroke and transient ischemic attacks; hyperglycemia; diabetes mellitus; metabolic

syndrome; hyperlipidemia (elevations in cholesterol, triglycerides); excessive weight gain; hyperprolactinemia; and increased risk of pituitary tumors. Such potential liability includes liability in actions by numerous states' attorneys general, discussed above, to recover, inter alia, "compensation for treating their citizens for alleged adverse reactions to RISPERDAL®."

84. J&J's own pre-clinical studies of Risperdal, as well as long-standing medical literature had demonstrated that the drug, like older antipsychotic medications, had the potential to cause diabetes, diabetes-related injuries (*e.g.*, weight gain and hyperglycemia), cardiovascular and cerebrovascular complications, and other severe adverse effects. Despite these known risks, J&J determined to conduct only the bare minimum of clinical trials, specifically designed to be of such limited duration that no side effects were likely to be revealed.

85. In addition, despite actual knowledge that Risperdal causes weight gain, which increases the risk of developing diabetes, for years J&J knowingly failed to include a Warning of the potential for weight gain and the possible development of diabetes as a result of the use of Risperdal in its U.S. labeling.

86. In October 2002, J&J, through its Janssen subsidiary, sent a letter to doctors and pharmacists in Canada describing the increased cardiovascular risk associated with the use of Risperdal, particularly in the elderly. Despite informing the Canadian medical community, J&J did not provide any notification to healthcare providers in the United States of this recognized material adverse risk until fourteen (14) months later, in November 2003.

87. Separately, in September 2003 the FDA mandated that manufacturers of all atypical antipsychotics include a warning concerning hyperglycemia and diabetes in labeling for the drugs, and to specifically call prescribers' attention to such warnings through a "Dear Doctor" letter.

88. As reflected in a Warning Letter from the FDA, dated April 19, 2004 and sent to both the CEO of Janssen Pharmaceutica and the CEO of J&J – Defendant Weldon, on November 6, 2003, J&J had submitted supplemental New Drug Approvals ("NDAs") to the FDA covering the addition of risk information to the Warnings section of the Product Insert ("PI") for Risperdal regarding hyperglycemia and diabetes. The FDA approved these supplements, and requested that J&J issue a DHCP (Dear Health Care Provider) letter "communicating the important new risk information."

89. Consistent with its policy to avoid, delay, or minimize taking patient safety actions that could adversely affect pharmaceutical sales, J&J instead issued a DHCP letter thatwas worded in such a false, misleading, and commercially self-serving manner that it was rejected by the FDA in the April 19 Warning Letter.

90. According to this Warning Letter, J&J's DHCP letter misled healthcare providers by, *inter alia*, (a) failing to communicate the fact that information regarding the potential consequences of hyperglycemia and the recommendation of regular glucose control monitoring was added to the PI for Risperdal; (b) minimizing the risks associated with the drug ; and (c) claiming that Risperdal was safer than other atypical antipsychotics when this had not been demonstrated by substantial evidence or substantial clinical experience .

91. The April 19 Warning Letter quoted a portion of the DHCP letter, finding that:

> This statement suggests that Risperdal does not increase the risks of diabeties, contradicting the Warning in the revised PI and minimizing the risks associated with the drug, including hyperglycemia-related adverse events such as ketoacidosis, hyperosmolar coma and death, and minimizing the importance of blood glucose control monitoring.

92. The FDA demanded that J&J immediately cease the dissemination of promotional materials for Risperdol containing claims similar to those previously touted, and provide a plan of action to correct the effects of its false and misleading DHCP letter.

93. The FDA further admonished J&J that the violations detailed above did not constitute an exhaustive list, and that it was continuing to "evaluate other aspects" of J&J's promotional campaign of Risperdal, and reserved the right to determine that "additional measures" would be necessary to "fully correct the false or misleading messages resulting from your violative conduct." It wasn't until July 2004 that the Company finally sent a "Dear Doctor" letter that was acceptable to the FDA.

94. The FDA's April 19, 2004 Warning Letter was not the first time J&J had been called to task for failure to provide adequate risk information about Risperdal. In the FDA's January 5, 1999 FDA Warning Letter concerning off-label promotion of Risperdal for use in geriatric patients, the FDA also charged J&J with failing to warn that the use of Risperdal by healthy elderly patients created a greater potential for hepatic and renal dysfunction and cardiovascular sensitivity, as well as making unsubstantiated claims of efficacy and comparative safety. Such conduct further evidences the Company's overall policy to avoid, delay, or minimize taking patient safety actions that could adversely affect pharmaceutical sales.

95. Consistent with this overall policy and with the Company's deliberate strategy to drive Risperdal sales through off-label promotion, despite data that emerged in 2005 regarding the increased risk of death and stroke in elderly patients treated with Risperdal and other atypical antipsychotics, according to the South Carolina complaint (filed May 2007), J&J continued to promote illegally the use of Risperdal for unapproved uses in such patients. J&J determined to press on with its off-label promotional campaign despite the risks of serious injury and death to

this vulnerable patient population. According to the Louisiana complaint, this course of conduct continued at least through the filing of that complaint in late August 2008.

96. As the result of J&J's knowing failure fully and properly to warn doctors and consumers of Risperdal's risks, many patients suffered Risperdal-related injuries and death, exposing J&J to substantial products liability. Such liability for failure to provide adequate warnings to patients is the direct result of the policy implemented by J&J's senior pharmaceutical division management, and its Executive Committee and senior corporate management, and knowingly permitted to continue by the Board, of avoiding, delaying, or minimizing patient safety actions that could adversely affect pharmaceutical sales.

97. Recent federal settlements of investigations of off-label promotion of atypical antipsychotic medications have yielded liabilities running into the billions of dollars, including the $1.42 billion January 2009 Eli Lilly & Co. settlement relating to the off-label promotion of Zyprexa, and the September 2009 $2.3 billion Pfizer, Inc. combined settlement relating to off-label promotion of Bextra, Geodon, Zyvox, and Lyrica. As evidenced by these settlements for comparable alleged misconduct, J&J faces potentially multi-billion dollar liabilities in connection with its knowing Risperdal Off-Label Promotion Scheme.

2. Natrecor

98. As noted above, one of the three federal subpoenas issued to J&J in March 2007 sought information regarding the sales and marketing of Natrecor by the Company and its Scios subsidiary, including information regarding the Company's corporate supervision and oversight of Scios's sales and marketing of Natrecor. This was not, however, the first time Defendants were aware of issues surrounding the sale and marketing of Natrecor.

99. In July 2005, Scios Inc. (Scios), a J&J subsidiary, received a subpoena from the United States Attorney's Office, District of Massachusetts, seeking documents related to the sales and marketing of Natrecor. The fact of this investigation was disclosed in the Company's Form 10-K for the fiscal year ended January 1, 2006, filed March 14, 2006 and signed by Defendants Weldon, Darretta, Poon, Coleman, Cullen, Johns, Jordan, Langbo, Lindquist, Mullin, Prince, Reinemund and Satcher.

100. In March 2007, almost a full two years after the first subpoena was received, the Company received yet another subpoena related to Natrecor, this time from the U.S. Attorney's Office in San Francisco. The subpoenas continued to request information about the sale and marketing of Natrecor, and also sought documents and information regarding the Company's corporate supervision and oversight of Scios. The fact of this investigation was disclosed in the Company's Form 10-K for fiscal year ended December 30, 2007, filed February 26, 2008 and signed by Defendants Weldon, Poon, Coleman, Cullen, Johns, Langbo, Lindquist, Mullin, Perez, Prince, Reinemund and Satcher,.

101. Natrecor was discovered and developed by Scios, a company J&J acquired in April 2003 for $2.5 billion. Scios's initial application for FDA approval of Natrecor was rejected in 1998 due to safety concerns, particularly relating to the drug's propensity to cause symptomatic hypotension (unusually low blood pressure).

102. In August 2001, the FDA approved Natrecor for a limited indication – the in-patient treatment of acutely decompensated congestive heart failure patients who have dyspnea at rest or with minimal activity. Recognizing that the limitation of use only to in-patient treatment would severely limit the commercial prospects for the drug – Scios developed an entire marketing plan around promoting Natrecor for regularly scheduled outpatient infusions, in part

by encouraging health care providers to open and operate their own outpatient Natrecor infusion clinics. Scios implemented this practice despite the known risks to patients and the absence of any scientific evidence that regularly scheduled outpatient infusions would offer any patient benefits.

103. At the time J&J acquired Scios, it was fully aware of this aggressive, illegal off-label promotion scheme, and, in fact, planned to continue and expand it upon acquiring the company (the "Natrecor Off-Label Promotion Scheme"). Reflecting this, in a February 10, 2003 joint press release announcing the acquisition agreement, J&J's then-Executive Committee member and Worldwide Chairman, Pharmaceuticals Group, Christine Poon, who would later become the Vice Chairman of the J&J Board in January 2005, stated "NATRECOR is a truly unique product for a largely underserved and growing market," and Richard B. Brewer, President and Chief Executive Officer of Scios, stated "Johnson & Johnson's financial and management resources will enable us to realize the full potential of NATRECOR." Later that day, Reuters reported that "[o]fficials from Johnson & Johnson and Scios said on a conference call with investors that they expect the partnership to help boost sales of Natrecor beyond current expectations."

104. The Company first disclosed that the federal government was investigating its sales and marketing of Natrecor in its Quarterly Report on Form 10-Q filed August 10, 2005. In its Annual Report on Form 10-K filed February 20, 2009, and signed by Defendants Weldon, Poon Coleman, Cullen Johns, Langbo, Lindquist, Mullin, Perez, Prince and Satcher, the Company first disclosed that the federal Natrecor investigation included a criminal investigation, with several former and current Scios employees called to testify before a grand jury in San Francisco. The February 2009 10-K failed to disclose, however, that one day prior to its filing,

three *qui tam* complaints against the Company concerning off-label promotion of Natrecor were unsealed.

105. In its Annual Report on Form 10-K filed March 1, 2010 and signed by Defendants Weldon, Coleman, Cullen, Johns, Langbo, Lindquist, Mullin, Perez, Prince and Satcher, the Company disclosed that: (a) the U.S. government has intervened in one of the *qui tam* actions, and filed a complaint against Scios and J&J in June 2009 (the "Federal Natrecor Complaint," attached as Exhibit 10 hereto, and incorporated by reference herein); and (b) Scios and J&J filed a motion to dismiss the Federal Natrecor Complaint, which motion was subsequently denied. The Form 10-K went on to report that the criminal investigation is continuing, and settlement discussions are underway.

106. The Federal Natrecor Complaint establishes that the scheme to illegally promote Natrecor for off-label use was approved and encouraged at the highest levels of J&J, including by J&J Chairman of the Board and CEO William Weldon. The Company acquired Scios following "comprehensive due diligence." (Scios Schedule 14a filed March 14, 2003). According to the Federal Natrecor Complaint:

> J&J was directly involved in Scios's marketing of Natrecor for serial, outpatient use. J&J knew and approved of Scios's marketing goals and strategies that included marketing Natrecor for serial, outpatient use. For example, even before the acquisition, J&J officers learned during the due diligence process that:
>
> a. The FDA had only approved Natrecor for treatment of acute congestive heart failure, not treatment of chronic congestive heart failure;
>
> b. Despite Natrecor's approved use, Scios was marketing Natrecor for serial outpatient use;
>
> c. There would be significant upside potential if Scios were able to achieve an indication for chronic outpatient use – i.e., the sales forecast would increase by $330 million (from $600 million to $930 million);

d. Scios's Business Plan included continuing to market Natrecor for outpatient use;

e. Success in the outpatient setting would depend on Medicare continuing to reimburse for "treatment on a chronic basis," and that until Medicare's view was clear, "it is a risk that is difficult to assess;" and

f. Scios was facilitating Medicare reimbursement for outpatient use through its Natrecor Reimbursement Quick Reference guide, its reimbursement support hotline, and its website, which also indicated that there was a financial incentive for physicians to use Natrecor in the outpatient setting.

107. Just after the acquisition, J&J and Scios jointly presented their plan to grow the outpatient congestive heart failure market to $100 million in 2004, $200 million in 2005, over $300 million in 2006, and over $400 million in 2007. This plan was a key component of J&J's plan to grow Scios's total revenue to over $1 billion by 2007. The Federal Natrecor Complaint alleges that J&J controls the business and daily operations of Scios.

108. Further evidencing J&J's direct involvement in Scios's illegal marketing of Natrecor for serial outpatient use, on June 27, 2003, the Chairman of J&J's Board of Directors, Bill Weldon, visited Scios and reviewed the 2003/2004 Natrecor Business Plan, which set out the plan to continue marketing Natrecor for outpatient use, and set separate sales goals for "Outpatient" sales.

109. Likewise, as detailed in the Federal Natrecor Complaint, in March 2004, J&J Company Group Chairman Joe Scodari reviewed and approved the 2004 Business Plan and Strategic Plan. The 2004 Business Plan, *inter alia*: (a) discussed the plan to continue marketing Natrecor for outpatient use by "[e]stablish[ing] a growing prescriber and advocate base that will drive Natrecor as the preferred management strategy in the outpatient setting (increase monthly infusion revenue from $3M to $9.5M);" (b) provides separate sales goals for "Acute CHF" sales and "Outpatient" sales, thereby differentiating outpatient infusions from the approved indication;

and (c) estimates that there are 129,000 eligible outpatient patients who may use 17 vials of Natrecor each, as opposed to 2.6 vials for each eligible "Acute CHF" patient.

110. The 2004 Strategic plan likewise discussed, *inter alia*: (a) Scios's "Development Strategy for Natrecor for the Chronic Intermittent Outpatient Market;" (b) "Leveraging the Natrecor Platform" for Outpatient Chronic CHF; (c) "Improv[ing] infusion procedure payment rate in hospital outpatient department;" and (d) "Increas[ing] business acumen of treating physicians."

111. Not only were members of J&J's senior executive management, including [Defendants] Weldon, Scodari and Poon, fully aware of the Natrecor Off-Label Promotion Scheme, at the time of the Scios acquisition, but so was J&J's Board, which approved the $2.5 billion cash offer to acquire Scios on the afternoon of February 9, 2005.

112. As disclosed in Scios' FY 2002 Annual Report on Form 10-K: "[s]ales of Natrecor represented approximately 96% of [Scios's] revenues for the year ended December 31, 2002," and "Natrecor [was] the only product that [Scios was] currently marketing." Given, *inter alia*: (a) the comprehensive due diligence J&J's Board performed prior to the acquisition; (b) the fact that Natrecor was Scios' only marketed product and virtually its only source of its revenues; (c) the public comments of Ms. Poon and Mr. Brewer as quoted above; and (d) the fact that the J&J Board approved the Company's final $45/share, $2.5 billion acquisition offer for the company, the J&J Board at that time was comprehensively briefed on Natrecor and J&J's post-merger plans for expanding its sale through continued pursuit and intensification of the Natrecor Off-Label Promotion Scheme.

113. According to the Federal Natrecor Complaint, since the April 2003 acquisition of Scios, J&J exercises strict supervision, control, and dominion over Scios's activities, decisions,

policies, and practices related to sales goals, sales tactics, compliance, regulatory affairs, medical affairs, research and development, human resources, legal issues, budget, accounting, employee compensation, employee benefits, employee expenses, manufacturing, and public relations.

114. In addition, J&J sets Scios's business objectives and sales goals and regularly reviews and approves Scios's sales numbers and projections. For example, in February 2004, J&J replaced Scios's President and CEO, Richard Brewer, with a J&J executive, Jim Mitchell, who confirmed to J&J that Scios's strategies included achieving the 2004 Business Plan, growing Natrecor's revenue to $1 billion by 2007.

115. Mitchell reports to a J&J Company Group Chairman, who, in turn, reports to J&J's Executive Committee and Board of Directors. Other members of Scios's Corporate Management Committee report directly to either to J&J or to Scios's President and CEO, who in turn, reports directly to J&J.

116. The Natrecor Off-Label Promotion Scheme continued and intensified following J&J's acquisition of Scios. As detailed above, on June 27, 2003, the Chairman of J&J's Board of Directors, Bill Weldon, visited Scios and reviewed the 2003/2004 Natrecor Business Plan. The 2004 Business Plan for Natrecor detailed strategies for achieving the goal of doubling the number of outpatient clinics providing Natrecor infusions.

117. One of these strategies was the "Centers for Excellence" program, under which J&J sent health care practitioners who were potentially interested in starting outpatient infusion clinics to existing outpatient clinics that used Natrecor, in order to observe and learn. As alleged in the Federal Natrecor Complaint, the 2004 Business Plan for Natrecor, reviewed and approved by Mr. Weldon, relied on the Centers of Excellence program as the primary tactic for achieving

the goal of "doubling the number of outpatient clinics delivering more than 20 infusions of Natrecor per month."

118. The same 2004 Natrecor Business Plan listed the ADHERE LM program, a registry of heart failure treatment and outcomes data created by Scios and continued by J&J as a vehicle to attract prescribers and promote the outpatient use of Natrecor, under the description: "Outpatient Management Market - Business Driver - Number of Treaters."

119. J&J pursued the Natrecor Off-Label Promotion Scheme through various tactics in addition to the Centers for Excellence and the ADHERE LM registry. For example, J&J and Scios maintained an Outpatient Infusion Center database from March 2003 to July 2004 to, *inter alia*, evaluate the market opportunity represented by outpatient infusion centers, measure the amount of Natrecor revenue being generated by outpatient infusion centers, and accelerate adoption of Natrecor in the outpatient infusion market.

120. In late 2003, Kim Hillis, Scios's Director of Sales, directed sales management to utilize Scientific Affairs Managers at the Company to help develop new Natrecor outpatient infusion clinics. During a sales representative training session in February 2004, J&J and Scios discussed separate sales goals for "Acute CHF" sales, and "Outpatient" sales, and their plan to continue marketing Natrecor for outpatient use by "establish[ing] a growing prescriber and advocate base that will drive Natrecor as the preferred management strategy in the outpatient setting."

121. J&J and Scios further instructed their sales force that the "Outpatient Market Development Strategy" was to maximize exposure to outpatient infusion data such as the FUSION I trial, to increase the number of individuals treated through Centers of Excellence

(discussed above), the ADHERE LM registry (discussed above), and the ongoing FUSION II clinical trial.

122. According to the Federal Natrecor Complaint, one of these Centers of Excellence was the South Bay Cardiovascular Associates ("South Bay"), located in West Islip, New York. From 2003 to 2005, J&J paid over $100,000 to a nurse at South Bay. This nurse made promotional speeches relating to the outpatient use of Natrecor; she trained other health care providers on the outpatient use of Natrecor; and her name appears as author on various publications relating to the outpatient use of Natrecor, including, *inter alia*, "Nesiritide in an Outpatient Infusion Clinic Setting – Case Studies of 17 patients," which was published in the Journal of Cardiac Failure in August 2002.

123. J&J paid numerous other health care professionals who authored articles, made promotional speeches, and/or taught continuing medical education courses that promoted the outpatient use of Natrecor. For example, from 2003 to 2005, J&J paid a cardiologist at Hackensack University Medical Center over $250,000. This doctor made speeches promoting the outpatient use of Natrecor, and was listed as author of articles on Natrecor, including at least two that were ghost-written at J&J's expense, including, among other articles, "Safety and Feasibility of Using Serial Infusions of Nesiritide for Heart Failure in an Outpatient Setting (From the FUSION I Trial)."

124. On or about May 2004, J&J paid a $500,000 grant to the University of Texas Southwestern Medical Center for a cardiology fellowship. A cardiologist at this Center was a key proponent of Natrecor outpatient infusions, authoring articles and giving speeches that promoted the outpatient use of Natrecor. Likewise, from 2003 to 2005, a cardiologist and former Medical Director at the Midwest Heart Specialists received over $160,000 from Scios and

J&J for speaking in favor of Natrecor. In addition, the Midwest Heart Foundation, which is affiliated with Midwest Heart Specialists, also received over $250,000 in grant funds from Scios.

125. These off-label promotion strategies succeeded in driving growth in Natrecor sales. For example, in January 2005, J&J estimated that Natrecor outpatient sales had increased by 173% for 2004 and would continue to increase by another 81% for 2005. The Company also estimated that its outpatient infusion business would grow at a higher rate than its base hospital business.

126. In February 2005, *Forbes.com* reported that "in 2004, sales of [Natrecor] more than doubled to $300 million according to Raymond James, an investment bank." *The New York Times*, on July 21, 2005, reported an even higher number – $400 million in Natrecor sales for 2004. J&J's aggressive and improper promotion tactics continued to drive accelerating growth in 2005 as well. For example, *Newsinferno.com* reported in August 2005 that: "Natrecor has been aggressively marketed with sales of the drug now reaching almost $700 million this year."

127. Even as it pursued these aggressive and highly successful off-label promotion strategies, according to the Federal Natrecor Complaint, J&J and Scios told the FDA in an April 11, 2005 letter that "Scios does not currently market Natrecor in a manner that suggests that it should or should not be used specifically in the outpatient setting," and that "Scios's written policies and training materials emphasize the company's unambiguous policy that the promotion of serial or scheduled administration of Natrecor is not permitted."

128. As also alleged in the Federal Natrecor Complaint, during the same year that J&J budgeted $750,000 for the Centers of Excellence program in an effort to double the number of outpatient clinics delivering more than 20 infusions of Natrecor per month, J&J provided the

FDA with slides from an October 12, 2004 training presentation indicating that the sales force was being trained not to market Natrecor for scheduled infusions.

129. This presentation, given by Scios's Senior Director, Health Care Compliance Naoko Fuji, stated that "we must not promote Natrecor for conditions requiring chronic, long-term or prophylactic therapy given that such promotion would not fall within the label indication currently approved for our drug."

130. These false claims of compliance with the law were directly at odds with J&J's actual long-term conduct, and underscore its knowledge of the law and the deliberate nature of its violations.

131. Of particular concern with respect to the Natrecor Off-Label Promotion Scheme is the fact it was pursued despite clear, known risks to patients, and without any scientific evidence that serial outpatient treatment provided any health benefits. As noted above, Scios' initial application for FDA approval of Natrecor was denied due to safety concerns, and when the FDA finally approved Natrecor, it did so for a narrow indication – the in-patient treatment of acutely decompensated congestive heart failure patients who have dyspnea at rest or with minimal activity.

132. The FDA required that the initial product labeling for Natrecor include a precaution that the drug should only be used in settings permitting the close monitoring of blood pressure.

133. Immediately after the launch of Natrecor in August 2001, Scios had started the FUSION I trial (derived from the study's full name – Management of Heart Failure after Hospitalization with Follow Up Serial Infusions of Nesiritide in an Outpatient Setting). FUSION I was a pilot study designed only to assess the ability of a patient with chronic congestive heart

failure to tolerate these serial infusions (*i.e.*, to study the safety of serial infusions) and thus was not a study that could be used to determine the efficacy of the serial infusions. Scios described the study as a multi-center (46 sites), randomized, three-treatment arm, open-label (thus the doctors and patients knew who were receiving Natrecor) pilot study of 210 chronic heart failure patients at high risk for rehospitilization. The patients generally had weekly outpatient visits for 12 weeks and the patients receiving Natrecor got a four to six hour infusion at each weekly visit.

134. In September 2003, six months after J&J had acquired Scios, the Company caused Scios to announce the results of FUSION I, stating that the study suggested that weekly outpatient infusions of Natrecor could be safely administered to treat high-risk patients with advanced CHF. While the study was not designed to support any conclusion about the efficacy of Natrecor for serial infusions, J&J caused Scios to issue a press release stating that "[d]ata from the FUSION I study suggests that the Natrecor-treated patients show improvements in clinical status with longer life expectancy and a lower frequency of hospitalizations compared to the group of patients receiving standard care." J&J, through Scios, disseminated the results of FUSION I widely, claiming that it supported not only the safety but the efficacy of Natrecor for serial infusions.

135. Thereafter, in 2004, J&J caused Scios to start a second trial on the outpatient use of Natrecor. Unlike FUSION I, FUSION II was a blinded and controlled study. It was also specifically designed to determine the efficacy of serial outpatient Natrecor infusions and to measure whether these infusions lowered mortality and hospitalization rates.

136. Meanwhile, as J&J aggressively expanded the population of patients exposed to Natrecor through its campaign to promote the drug off-label for serial outpatient infusions – concerns about Natrecor's safety increased. In early 2004, the FDA requested that a panel of

experts be convened to discuss, among other topics, the use of Natrecor in outpatient settings and dose/response relationships for the drug. In response , in June 2004, Scios and J&J convened a panel of ten prominent cardiologists, led by Dr. Eugene Braunwald of Harvard Medical School, to review Natrecor's safety and efficacy, and to make recommendations concerning the use and further clinical studies of the drug (the "Special Advisory Panel").

137. As reported by *The New York Times* on August 9, 2005:

> Rather than the milquetoast findings often returned by such advisory panels, Dr. Braunwald's committee of 10 medical experts determined that use of Natrecor, an expensive intravenous therapy, should be strictly limited to acutely ill patients in hospitals. The committee asked Scios to begin warning doctors against the drug's use in outpatients, a treatment that had not been approved by the Food and Drug Administration but that had helped turn Natrecor into a big money maker.

138. On June 13, 2005, the Special Advisory Panel recommended that Scios and J&J proceed with their current clinical trial program, but also recommended an additional trial to assess the effect of Natrecor on survival because the evidence was insufficient and inconclusive regarding the long-term safety of Natrecor.

139. Consistent with the Company's overall policy to avoid, delay, or minimize taking patient safety actions that could adversely affect pharmaceutical sales, J&J initially resisted the Special Advisory Panel's recommendation that outpatient use of Natrecor be discontinued. J&J orchestrated and controlled Scios's response to the Panel's criticism of Natrecor's use in the outpatient setting and recommendation, *inter alia*, that the drug be used strictly in the inpatient setting.

140. As *The New York Times* article reported:

> Some committee members said that their concerns about Scios's handling of their recommendations began soon after the panel reported its findings to the company on June 13. The report's crucial finding was unambiguous. Natrecor should not be used in outpatients.

> But rather than simply disseminate the report, Scios created its own prefacing news release. The committee's conclusion that Natrecor should not be used in outpatient settings was not clearly stated until the final page of the five-page company document. Instead, the news release played up the panel's recommendation that Scios gather further data by continuing with a clinical trial, called Fusion II, to determine the drug's usefulness in outpatients.
>
> "The press release emphasized a small aspect of our recommendations - that clinical trials should continue; it de-emphasized or made little mention of the more important take-home points of our recommendations," said Dr. Milton Packer, a cardiologist at the University of Texas Southwestern Medical Center in Dallas who served on the committee.
>
> Dr. Packer also said that the committee members were shocked several weeks later when they received invitations as part of a mass mailing to enroll in a continuing medical education program, financed by Scios, that seemed to promote the outpatient use of Natrecor, whose chemical name is nesiritide.
>
> "We were flabbergasted." Dr. Packer said. "Scios was sponsoring meetings to discuss nesiritide and its potential use in outpatients."

141. On July 20, 2005, Dr. Braunwald of the Special Advisory Panel sent a letter to Dr. Randall Kaye, Scios's Vice President of Medical Affairs, stating that "members of the Natrecor Advisory Panel have been disturbed by what we consider to be significant omissions and lack of clarity in Scios'[s] efforts to comply with the Panel's recommendations."

142. On July 28, 2005, J&J Worldwide Chairman, Pharmaceuticals Group and Executive Committee Member, Defendant Scodari, instituted a communications team comprised mostly of J&J employees to oversee the response to the Special Advisory Panel's recommendations and all communications about Natrecor. Scodari further ordered and participated in the team's weekly conference calls, and instructed Scios's President and CEO to "ensure a review on the *return* to promoting the on-label outpatient use (acute) is conducted" in Scios's 2006 Strategic Plan (emphasis in Federal Natrecor Complaint, ¶104).

143. In March 2006, the federal Centers for Medicare & Medicaid Services issued a national coverage determination denying coverage for outpatient use of Natrecor, stating:

> Much of the reported research on the use of nesiritide for the intermittent treatment of chronic heart failure appears in abstracts and has not yet been published as full peer-reviewed journal articles. In general, abstracts do not provide sufficient information for us to evaluate the strength of the reported findings critically. As such, these abstracts do not constitute strong evidence and are given less weight than other evidence. The published articles supporting the off-label use of nesiritide for chronic heart failure are hampered by methodological shortcomings, including small sample size and the lack of long term outcome data. . . . These weaknesses, along with the incidence of renal dysfunction, the increased incidence of mortality, and the findings and recommendations of the Nesiritide Advisory Panel create substantial concerns about the net health outcomes associated with the use of this drug for chronic heart failure. . . .CMS has determined that there is sufficient evidence to conclude that the use of nesiritide for the treatment of chronic heart failure is not reasonable and necessary for Medicare beneficiaries in any setting."

144. Finally, in 2007, Scios released the results of its FUSION II clinical trial. The study did not show any significant benefits of serial outpatient Natrecor infusions in comparison to standard care. In other words, not only did Scios and J&J aggressively expand public exposure to Natrecor through an illegal off-label promotion campaign for outpatient use despite significant health risks, but also despite the absence of any evidence that such use would benefit patients. The Natrecor Off-Label Promotion Scheme is thus a poignant example of the Company's overall policy to elevate its commercial goals over significant legal and ethical issues concerning patient health benefits and patient health risks.

145. On November 29, 2007, J&J announced that it would record a $440 million write down due to declining Natrecor sales. *The New York Times* reported that the Company explained that sales had declined significantly since outside medical researchers raised questions in 2005 about possible increased risk of kidney problems and death associated with the drug.

146. The Natrecor Off-Label Promotion Scheme stands as an example of the willingness of the Board and J&J's most senior executive officers, including Officer Defendants Weldon, Poon and Scodari, to knowingly pursue unlawful and unethical strategies, and to ignore ethical issues concerning patient health benefits and patient health risks, in their pursuit of short term financial performance. The $2.5 billion Scios acquisition was presented to the Board on February 9, 2003 after comprehensive due diligence had, necessarily, revealed five fundamental facts: (a) Natrecor was Scios' sole marketed drug and virtually its sole source of revenues, (b) Natrecor posed significant risks for patients and consequently had been approved by the FDA for a narrow and commercially limiting indication, (c) plans to grow Natrecor revenues depended on continuing and expanding Scios' promotion of Natrecor for off-label use in the outpatient serial infusion setting, (d) FUSION I had not yet been completed and thus the safety of Natrecor in the outpatient serial infusion setting had not yet been shown, and (e) no adequate and well-controlled clinical study had shown any patient benefit, over standard care, from outpatient serial infusion treatment with Natrecor.

147. The Board was apprised of these fundamental facts and approved the acquisition that same day. The ease and speed with which the Board approved this course of action is further evidence that the Director Defendants were fully aware, and in approval of, J&J's consistent strategy of off-label promotion of drugs and medical devices, which as of the February 2003 Scios acquisition, was already being applied across the Company in the Risperdal Off-Label Promotion Scheme (discussed supra), the Topamax Off-Label Promotion Scheme (discussed infra) and the Biliary Stent Off-Label PromotionScheme (discussed *infra*).

148. Now, as the result of the willingness of the Board and J&J's most senior executive officers to complete the Scios acquisition and pursue and expand the off-label

promotion of Natrecor, and the willingness of senior management and the Board to continue this strategy at least through the summer of 2005, J&J faces liabilities to the federal government for the illegal Natrecor Off-Label Promotion Scheme potentially amounting to hundreds of millions of dollars.

149. By knowingly pursuing the Natrecor Off-Label Promotion Scheme, the Officer Defendants, including Weldon, Poon and Scodari, breached their fiduciary duty of loyalty and good faith. By knowingly permitting them to do so, the Director Defendants breached their fiduciary duty of loyalty and good faith. Such breaches of fiduciary duty have proximately caused the Company to suffer damages in an amount to be determined at trial, for which the Officer Defendants and the Director Defendants are fully accountable.

3. Topamax

150. As reported in the Annual Report on Form 10-K for the fiscal year ended December 31, 2003, filed on March 11, 2004 and signed by Defendants Weldon, Darretta, Coleman, Cullen, Jordan, Langbo, Linquist, Mullin, Reinemund, Satcher and Schacht, the Company has been under investigation for off-label promotion of Topamax since at least December 2003. That filing disclosed that "[o]n December 8, 2003, the Company's Ortho-McNeil Pharmaceutical unit received a subpoena from the United States Attorney's office in Boston, Massachusetts seeking documents relating to the marketing, including alleged off-label marketing, of the drug TOPAMAX (topiramate) which is approved for anti-epilepsy therapy" (the "Topamax Off-Label Promotion Scheme").

151. Further, on July 27, 2004, the Company received a letter request from the New York State Attorney General's Office for documents pertaining to marketing, off-label sales and clinical trials for Topamax (along with Risperdal, Procrit, Reminyl, Remicade and Aciphex.

This additional investigation into off-label marketing and sales of Topomax was disclosed in the Company's Annual Report for the fiscal year ending January 2, 2005, filed March 15, 2005, and signed by Defendants Weldon, Darretta, Coleman, Cullen, Jordan, Langbo, Lindquist, Mullin, Reinemund, Satcher and Schacht.

152. A full three years later, and despite the fact that Defendants were aware of the governmental investigations into the Company's sales and marketing practices across a wide spectrum of drugs, including but not limited to Topamax, by at least early 2004, the Company received yet another subpoena in March of 2007. This time, the subpoena was from the U.S. Attorney's Office in Boston, and requested information not only regarding the sales and marketing of Topamax, but also regarding the Company's corporate supervision and oversight of Ortho-McNeil, the subsidiary charged with selling Topamax. The fact of this additional subpoena was disclosed in the annual report for the fiscal year ended December 30, 2007, filed February 26, 2008, and signed by Defendants Weldon, Poon, Coleman, Cullen, Johns, Langbo, Lindquist, Mullin, Perez, Prince, Reinemund and Satcher.

153. As discussed above, the March 2007 subpoena was part of a coordinated investigation involving three separate U.S. Attorney's Offices, spanning three J&J subsidiaries and involving three different drugs, focusing on J&J's lack of supervision and oversight of the three subsidiaries involved in the promotion, sales and marketing of Topamax, Risperdal and Natrecor. According to the Company's most recent Annual Report on Form 10-K, the Topamax investigation has included testimony by current and former J&J employees before a federal grand jury, and settlement discussions are underway.

154. Topamax was first approved by the FDA in December 1996 for the treatment of seizures. In August 2004, the FDA approved Topamax for the prevention of migraines. Despite

these limited indications, pursuant to the Topamax Off-Label Promotion Scheme, J&J successfully generated substantial off-label demand for the drug.

155. As a result of this scheme, Topamax has been prescribed extensively for numerous off-label indications, including treatment of bipolar disorder, to counteract weight gain associated with numerous antidepressants, treatment of alcoholism, treatment of obesity, treatment of binge eating, treatment of posttraumatic stress disorder, treatment in the prevention of periventricular leukomalacia in preterm infants after an hypoxic-ischemic injury, the treatment of essential tremor, bulimia nervosa, obsessive-compulsive disorder, smoking cessation, idiopathic intracranial hypertension, neuropathic pain, cluster headache, and cocaine dependence. An analysis reported by Knight-Ridder in 2003 found that 79% of all prescriptions for Topamax were for off-label uses.

156. Topamax sales grew explosively, from $687 million in 2002 to over $2.7 billion in 2008, the year before its patent expiration.

157. In September 2004, J&J received a Warning Letter from the FDA concerning a serious violation of law by J&J in its marketing materials for Topamax. This letter was copied to William Weldon, Chairman of the Board and CEO of J&J. The Warning Letter stated that the Company's Topamax promotional materials "fail to present any information about the risks of oligohidrosis, hyperthermia, and metabolic acidosis," which are "very serious risks."

158. The September 2004 Warning Letter went on to emphasize that "it is also noteworthy that the majority of reports of these adverse reactions have been in children," and demanded that J&J withdraw these false and misleading promotional materials from circulation and respond with a plan of action to disseminate complete Topamax risk information to the audiences exposed to the misleading materials.

159. The Company's failure to warn patients and prescribers about these "very serious risks" of treatment with Topamax is yet another example of the Company's policy to avoid, delay, or minimize taking patient safety actions that could adversely affect pharmaceutical sales, thus elevating commercial goals over issues of patient heath benefits and patient health risks.

160. Despite the knowledge by J&J's Board of the federal investigation of the Company's illegal off-label promotion of Topamax, the Company continued with its aggressive efforts to generate off-label demand for the drug at least into late 2007.

161. On October 9, 2007, the public interest group Public Citizen wrote a letter to the FDA urging it to take action against "the illegal and dangerous promotional campaign by Ortho-McNeil Janssen-funded researchers for the unapproved use of Topamax (topiramate) for treating alcoholics." The Public Citizen letter is attached at Exhibit 11 hereto, and is incorporated by reference hereto. The letter went on to state:

> In a study to be published in tomorrow's Journal of the American Medical Association, funded entirely by the company, researchers from the company and from the University of Virginia find only a modest improvement in the percentage of days of heavy drinking in people using Topamax compared with people using a placebo. Both groups also got a weekly 15 minute intervention by a trained nurse to promote compliance. But accompanying the study, in an embargoed press kit distributed by the University of Virginia on behalf of the researchers, is a question and answer sheet asking "Can my doctor prescribe me topiramate for alcohol dependence?" The answer is, essentially, yes: "Since topiramate is currently FDA-approved for seizures and migraines, it is available to your doctor to prescribe it to you off-label." This clearly violates the prohibition on off-label promotion, as patients are being explicitly urged/promoted to ask their doctor for topiramate to treat their serious alcohol addiction.

162. The Public Citizen letter went on to highlight serious, adverse side effects of Topamax use, including metabolic acidosis, eye problems, increased body temperature, and kidney stones, and urged that "[s]uch reckless disregard for Federal law and regulations should not be tolerated."

163. As noted above, in addition to the long-running federal investigation of J&J's off-label promotion of Topamax, the Company has also been charged with disseminating false and misleading promotional materials omitting required disclosures of serious health risks associated with the use of Topamax.

164. In light of the multibillion dollar sales of Topamax during the relevant period, the high percentage of Topamax prescriptions attributed to off-label uses, and the persistent nature of J&J's illegal activities even after its Board was on notice of the federal investigation, J&J faces substantial liability exposure of potentially $1 billion or more in connection with the federal investigation of the Topamax Off-Label Promotion Scheme.

C. The DePuy Kickback Scheme

165. On September 27, 2007, the Department of Health and Human Services Office of the Inspector General filed a criminal complaint in the United States District Court for the District of New Jersey (the "Criminal Complaint," attached as Exhibit 12 hereto, and incorporated by reference herein).

166. Pursuant to the settlement between the government and the Company, in September 2007 J&J was forced to pay $84.7 million, and its DePuy Orthopaedics subsidiary was charged with conspiracy to violate the federal Anti-Kickback Statute and forced to enter into a deferred prosecution agreement and a Corporate Integrity Agreement in a combined resolution of criminal and civil charges for paying and offering inducements to orthopedic surgeons to use DePuy hip and knee joint reconstruction and replacement products (the "DePuy Kickback Scheme").

167. According to the Criminal Complaint, the Company operated this kickback scheme from January 2002 to December 2006.

168. The Company disclosed in its May 10, 2005 Form 10-Q that "in March 2005, DePuy Orthopaedics, Inc. (DePuy), a Johnson & Johnson subsidiary, received a subpoena from the U.S. Attorney's Office, District of New Jersey, seeking records concerning contractual relationships between DePuy and surgeons or surgeons in training involved in hip and knee replacement and reconstructive surgery."

169. This same disclosure was made in the Fiscal Year 2005 Annual Report on Form 10-K, signed by Defendants Weldon, Darretta, Poon, Coleman, Cullen, Johns, Jordan, Langbo, Lindquist, Mullin, Prince, Reinenumd and Satcher.

170. Despite the knowledge of J&J Board's of the DePuy investigation, the illegal conduct was permitted to continue until December 2006.

D. The Biliary Stent Off-Label Promotion Scheme

171. From in or about 1996 through at least 2007, J&J also pursued its unlawful off-label marketing strategy to drive sales of medical devices known as biliary stents, (the "Biliary Stent Off-Label Promotion Scheme"), through its subsidiary, Cordis Corporation. On September 26, 2006, a *qui tam* action was filed on behalf of, *inter alia*, the United States in the Northern District of Texas, under the False Claim Act (the "Biliary Stent Complaint," attached as Exhibit 13 hereto, and incorporated by reference herein) to recover damages, penalties and other remedies in connection with a biliary stent off-label promotional and marketing scheme pursued by multiple companies, including J&J, by and through Cordis Corporation and its Cordis Endovascular division.

172. As is true with respect to all of its subsidiaries, J&J dominates and controls all policies, practices and activities of Cordis Corporation and its wholly owned subsidiary, Cordis Endovascular.

173. Biliary stents are medical devices implanted in the bile duct. Several thousand patients are diagnosed annually with terminal biliary cancer resulting in poor flow of the bile duct. Patients experience drainage issues in the bile duct resulting in painful, ancillary medical symptoms, and life expectancy is limited. The biliary stent, a Class II medical device, is a temporary, palliative medical device implanted in the bile duct to keep it open.

174. Vascular stents, on the other hand, are functionally and compositionally different than biliary stents. Vascular stents (also known as intravascular or endovascular stents) are classified by the FDA as Class III medical devices that pose significant risks to patients. They are implanted permanently into patients' vascular systems to treat peripheral vascular disease by enhancing vessel patency and reducing early restenosis over the life of the device. Pursuant to the Biliary Stent Off-Label Promotion Scheme, J&J promoted biliary stents for off-label use in the human vascular system and caused and induced physicians to seek coverage and reimbursement for such use.

175. In contrast to the few thousand patients annually with cancer in the biliary tree, hundreds of thousands of patients are diagnosed annually with vascular disease. Most live decades. Unlike biliary stents, vascular stents, as Class III medical devices that pose significant risks to patients, require premarket approval (PMA) from the FDA before marketing the devices. Premarket approval is the most stringent regulatory review reserved for high-risk devices. It requires device manufacturers to clinically establish the safety and efficacy of the devices in patients. It is a lengthy, costly process which J&J sought to avoid pursuant to the Biliary Stent Off-Label Promotion Scheme.

176. In conceiving the Biliary Stent Off-Label Promotion Scheme, J&J saw an opportunity to circumvent the expensive mandatory premarket approval process for Class III

vascular stents by falsely claiming that stents it fully intended to promote and sell for vascular use were not vascular stents, but instead were biliary stents. The Biliary Stent Complaint alleges that, recognizing this opportunity, J&J, as well as competing companies, developed stents with the intent to promote and market the devices for the treatment of vascular disease. They filed for patent protection with the United States Patent and Trademark Office certifying to claims that the devices were intended for vascular disease and use in the human vascular system. No claims were made for palliation of malignant strictures of the biliary tree. J&J and its competitors then knowingly filed fraudulent section 510(k) premarket clearance notifications with the FDA, falsely certifying that the devices were only biliary stents for use in the palliation of malignant biliary strictures.

177. The Biliary Stent Off-Label Promotion Scheme also provided a means to circumvent federal statutory requirements to conduct post-market surveillance of medical devices that are marketed and promoted for a Class III indication requiring premarket approval. Pursuant to the Safe Medical Devices Act of1990 and the Food and Drug Administration Modernization Act of 1997, Defendants avoidance of statutorily required post-market surveillance further concealed Defendants' fraudulent scheme and the true extent of the safety and efficacy issues raised for beneficiaries by marketing the unapproved biliary stents as intended for use in the vascular system. Thus, the Biliary Stent Off-Label Promotion Scheme is yet another example of J&J's deliberate policy of sidestepping laws and regulations designed to safeguard patient health in order to drive commercial profits.

178. The FDA has not approved biliary stents for use in peripheral vasculature. Biliary stents are not vascular stents by intended use, by FDA classification, and by Medicare coverage. In fact, the FDA concluded that biliary stents are not safe or effective for vascular use, and the

FDA required these companies, including J&J, to clearly and prominently warn physicians of the safety and efficacy risks to patients when marketing the stents.

179. To effectuate the Biliary Stent Off-Label Promotion Scheme, beginning in 1996, and continuing through at least 2006, J&J caused Cordis to file fraudulent pre-market clearance notifications with the FDA, certifying that the devices covered by each notice were only biliary stents intended for use in the palliation of malignant strictures of the biliary tree when, in fact, J&J intended to market the devices for use in peripheral vasculature. Such false pre-market clearance notifications are identified in the following chart in reverse chronological order:

BILIARY STENT NAME	510K	DATE
Palmaz Blue .014 Transhepatic Biliary Stent System	K060877	4/27/06
Smart Control Nitinol Stent Transhepatic Biliary System	K042969	11/8/04
Precise Rx Nitinol Stent Transhepatic Biliary System	K041796	8/3/04
Cordis Palmax Blue .018 Transhepatic Biliary Stent	K040413	6/21/04
Cordis Palmaz Genesis Transhepatic Biliary Stent	K033394	12/22/03
Precise Rx Nitinol Stent Transhepatic Biliary System	K032137	9/17/03
Smart Control Nitinol Stent Transhepatic Biliary System	K032457	9/4/03
Smart Control Nitinol Stent Transhepatic Biliary System	K031777	7/7/03
Smart Control Nitinol Stent Transhepatic Biliary System	K031197	6/16/03
Smart Control Nitinol Stent Transhepatic Biliary System	K023217	10/25/02
Smart Control Nitinol Stent Transhepatic Biliary Stent	K021898	81402
Cordis Palmaz Genesis Transhepatic Biliary Stent	K021345	6/28/02
Cordis Palmaz Genesis Transhepatic Biliary Stent	K020809	4/12/02
Smart Nitinol Stent Transhepatic Biliary System	K020052	2/11/02
Precise Nitinol Stent Transhepatic Biliary System	K012993	10/5/01
Cordis Palmaz Genesis Transhepatic Biliary Stent	K012590	9/7/01
Palmaz Genesis Transhepatic Biliary Stent and Delivery System	K010411	8/27/01
Cordis Palmaz Genesis Transhepatic Biliary Stent	K012056	8/1/01
Cordis Palmaz Genesis Transhepatic Biliary Stent	K012087	8/1/01
Cordis Palmaz Genesis Transhepatic Biliary Stent	K012090	8/1/01
Precise Nitinol Stent Transhepatic Biliary System	K010445	3/16/01
S.M.A.R.T. Nitinol Stent Transhepatic Biliary System	K03336	11/22/00
S.M.A.R.T. Nitinol Stent Transhepatic Biliary System	K001843	7/18/00
Rx Transhepatic Biliary Stent and Delivery System	K001258	6/27/00
Cordis Medium Palmaz Transhepatic Biliary Stent and Delivery System	K000564	3/23/00
Cordis Palmaz Corinthian Iq Transhepatic Biliary Stent	K994156	1/7/00

S.M.A.R.T. Nitinol Stent Transhepatic Biliary System	K994068	12/23/99
S.M.A.R.T. .018 Nitinol Stent Transhepatic Biliary System	K993646	11/18/99
Palmaz X1 Transhepatic Biliary Stents	K993091	10/29/99
Cordis Palmaz Corinthian Transhepatic Biliary Stent and Delivery System	K992755	9/15/99
Cordis Palmaz Corinthian Transhepatic Biliary Stent and Delivery System	K991674	8/12/99
Cordis Palmaz Corinthian Transhepatic Biliary Stent and Delivery System	K991028	8/4/99
Cordis Palmaz Corinthian Transhepatic Biliary Stent and Delivery System	K990631	4/30/00
Cordis Nitinol Stent and Delivery System	K980823	12/18/98
Perflex Stainless Steel Stent and Delivery System	K980653	6/8/98
Palmaz and Palmaz-Schatz Balloon-Expandable Stents	K964688	6/20/97
Cordis Biliary Stent	K955728	5/8/96

180. In each of these section 510(k) premarket clearance notifications, J&J falsely certified to the FDA that the device "is intended for use in the palliation of malignant neoplasms in the biliary tree." The section 510(k) premarket clearance notifications concealed and failed to disclose that J&J intended for these devices to be used as vascular stents in the vascular system. Based on these false certifications and statements, the FDA issued a premarket clearance letter for each of the above-listed devices, limited to the stated intended use and imposing restrictions on J&J prohibiting it from marketing or promoting the device as an FDA approved vascular stent.

181. The FDA granted premarket clearance for the biliary stents under section 510(k), limited to palliation of malignant strictures of the biliary tree. None of the devices was pre-market approved by the FDA as a Class III vascular stent intended for use in the peripheral vascular system. Instead, the FDA required J&J to prominently disclose in labeling, marketing and promotional materials that "[t]he safety and effectiveness of this device for use in the vascular system have not been established."

182. J&J's competitors in the vascular stent market, also named as defendants in the Biliary Stent Complaint, followed an identical course of action, fraudulently obtaining premarket clearance letters.

183. Enabled with section 510(k) premarket clearances for the biliary stents, J&J and its competitors then actively promoted and marketed the devices off-label as vascular stents intended to treat peripheral vascular disease, using the following measures:

(a) instructing sales representatives to target physicians specializing in peripheral vascular disease to induce the use of the Class II biliary stents as unapproved Class III vascular stent intended for vascular disease;

(b) directly or indirectly sponsoring or funding studies of the off-label use of the biliary stents to treat peripheral vascular disease and providing the study information to sales representatives for use in marketing and promoting the devices to vascular physicians;

(c) extensively marketing and promoting the devices in print and electronic advertisements targeting physicians with vascular specialization in an effort to solicit the use of the devices for the vascular system, with simultaneously avoiding any print and electronic marketing of the biliary stents targeted to gastroenterologists and hepatologists (physicians specializing in biliary tree disorders);

(d) providing unsolicited marketing and promotional literature to physicians concerning the off-label use of the unapproved biliary stents to treat vascular disease, including information advising physicians how to develop and expand a

peripheral vascular practice, thereby encouraging the unapproved use of the biliary stents;

(e) preparing patient "advisory" letters and similar documents concerning the health risks of undiagnosed and untreated peripheral vascular disease, provided to vascular specialists, without solicitation, to send to patients to generate patient interest in peripheral vascular disease and to induce the unapproved use of the biliary stents;

(f) giving sales representatives mandatory quotas requiring them to sell the biliary stents off-label simply to satisfy the quota;

(g) establishing compensation schemes for sales representatives which included bonuses for off-label sales; and

(h) providing reimbursement guidelines and manuals to physicians that instructed physicians to falsely code reimbursement claims using procedural codes for approved vascular stents, even though an unapproved biliary stent was utilized.

184. Further supporting the knowing and systemic nature of this off-label promotion at J&J, the Biliary Stent Complaint discloses that Cordis trained its sales representatives by placing them in a vascular laboratory where the physician would teach them how to read vascular angiograms and let the reps watch live peripheral vascular cases.

185. J&J and its competitors were highly successful in the off-label scheme. In excess of 700 biliary stent product codes made by these companies have been promoted and marketed off-label for treating peripheral vascular disease, even though more than 500 of these biliary stent product codes cannot be used in the biliary tree due to the length and diameter of the

device. Indeed, virtually all of the approximate 150,000 stents implanted in patients each year to treat vascular disease are adulterated and misbranded biliary stents.

186. In an article published on January 14, 2010, the New York Times reported that "[a] 2008 study in a medical journal, the American Journal of Therapeutics, estimated that one million biliary stents were used off-label from 2003 to 2006 to open clogged blood vessels in other parts of the body. That report also found that deaths and injuries had occurred as a result of device malfunctions when the stents were used off-label."

187. The adverse events reported as a result of the improper implanting of biliary stents have included death, fractures of the devices after implantation, migration and dislodgement of the devices after implantation, arterial dissection and occlusion, arterial and stent embolizations, aneurysms, acute renal insufficiency, amputations, air embolisms, fistulization, strokes, late restenosis, allergic reactions, infections, clots, internal bleeding, and persistent vessel spasms, among other serious medical conditions.

188. In an article published on March 10, 2007, *The Wall Street Journal* reported that "[i]n 2004, the FDA forced J&J's Cordis unit to recall an instruction sheet, which wasn't approved by the FDA, for its Precise biliary stent after nine off-label patients were injured."

189. That same March 2007 article reported that the FDA "has called a meeting with makers of bile-duct stents to discuss their heavy use for unapproved, or "off label" surgical applications." In its January 14, 2010 article, the New York Times reported that "[i]n 2007, the F.D.A. warned biliary device manufacturers about promoting them for vascular use."

190. J&J has disclosed in its Form 10-K for the fiscal year ended December 28, 2008, filed February 20, 2009 and signed by Defendants Weldon, Poon, Coleman, Cullen, Johns, Langbo, Lindquist, Mullin, Perez, Prince and Satcher, that in June 2008, the Company received a

subpoena from the United States Attorneys' Office for the District of Massachusetts relating to the marketing of biliary stents by J&J's Cordis subsidiary.

191. As a result of the knowing unlawful conduct represented by the Biliary Stent Off-Label Promotion Scheme, representing a breach of the fiduciary duty of loyalty by the Officer and Director Defendants herein, the Company has suffered damages in an amount to be determined at trial.

E. The 2010 Product Odor Recalls and Defendants' Inadequate Response to Prior Complaints

192. On January 15, 2010, the San Juan District Office of the FDA issued a Warning Letter to the Company's McNeil Consumer Healthcare business unit. The subject of the Warning Letter was the Company's violation of cGMP regulations in connection with the failure to adequately investigate and report to the FDA consumer complaints relating to an "uncharacteristic odor" and related adverse patient health events due to contamination of over-the-counter ("OTC") products.

193. This Warning Letter, copied to J&J Chairman of the Board and CEO William Weldon, charges not only that McNeil Consumer Healthcare violated cGMP regulations, but also that J&J's response at the parent company level was inadequate, specifically finding that:

> The Agency is concerned about the response of Johnson & Johnson (J&J) to this matter. It appears that when J&J became aware of FDA's concerns about the thoroughness and timeliness of McNeil's investigation, whether all potentially affected products had been identified, and whether the recall was adequate in scope, J&J did not take appropriate actions to resolve these issues. Corporate management has the responsibility to ensure the quality, safety, and integrity of its products. Neither upper management at J&J nor at McNeil Consumer Healthcare assured timely investigation and resolution of the issues.

194. The Warning Letter detailed several violations indicative of systemic compliance management deficiencies. These charges included:

(a) The initial investigation into the root cause of the odor was unjustifiably delayed and terminated prematurely. Numerous complaints were received over a four month period in 2008 before they were considered a trend and before actions were initiated to determine the root cause. When microbiological testing in August 2008 did not support an initial speculation that microbial contamination was the root cause of the odor, the investigation was closed. No other possible root causes were pursued. The Company lacked adequate justification for this decision.

(b) Complaints of uncharacteristic odor were reported again in April 2009. Approximately 112 similar complaints were received by August 3, 2009. Although J&J had test results indicative of contamination with TBA as the source of the off odor on the complaint samples since September 2009, these results were not shared with FDA until after the initiation of the inspection and following several requests for this information made by the district office.

(c) In October 2009, J&J concluded that the most probable root cause of the odor in the Tylenol Arthritis Relief caplets was the exposure of drug product bottles to wood pallets chemically treated with TBP. The Company did not expand the scope of the investigation to other lots and products potentially affected by this deviation.

(d) The timing and depth of J&J's investigative efforts regarding uncharacteristic odor complaints were insufficient to meet good manufacturing practice. J&J's management, including the Quality Control Unit, was not proactive in response to consumer complaints. In addition, during the 2008 examination of complaint samples, J&J's analysts noted that the tablets, once removed from the bottle, did

not have an unusual odor but the bottle retained a strong odor. Nonetheless, J&J did not pursue chemical testing at that time.

(e) J&J's quality management should have ensured the start of chemical testing far earlier. Failure to do so prolonged identification and resolution of the problem, resulting in continued consumer exposure.

(f) J&J received numerous uncharacteristic odor consumer complaints during the period of April 2008 through September 2008 for Tylenol Arthritis Relief caplets. Nevertheless, J&J failed to submit a FAR to FDA within three working days to inform the agency of the nature of the problem and the steps being taken to address it. J&J did not submit the FAR until September 18, 2009, after again noting an adverse, continuing trend of numerous complaints over the course of a several month period.

195. As the result of the Company's inadequate cGMP compliance procedures, the Company was forced to conduct a broad recall of potentially affected products, in "consultation with the FDA," which it announced on the date of the FDA Warning Letter.

196. The Company had previously conducted a prior, limited recall in 2009 based on the cursory investigation criticized in the FDA Warning Letter.

197. The Company's mishandling of this product contamination incident (the "Delayed OTC Contamination Recall Scheme") has caused substantial financial harm to the Company as well as injury to its reputation and goodwill and its relations with its primary regulator, the FDA.

V. DERIVATIVE ALLEGATIONS

A. General Derivative Allegations

198. Plaintiff brings this action derivatively in the right and for the benefit of J&J to redress the breaches of fiduciary by Defendants as alleged herein.

199. Plaintiff owns and has continuously owned common stock in J&J throughout the period of the wrongdoing.

200. This action is not a collusive one to confer jurisdiction that the court would otherwise lack.

201. Plaintiff will adequately and fairly represent the interests of J&J and its shareholders in enforcing and prosecuting its rights, and has retained counsel experienced in prosecuting this type of action.

B. Pre-Suit Demand is Futile

202. Plaintiff incorporates by reference all preceding and subsequent paragraphs, and all documents incorporated by reference herein, as though they were fully set forth herein.

203. At the time this action was initiated, the Board was comprised of eleven (11) directors: Defendants Coleman, Cullen, Johns, Langbo, Lindquist, Mullen, Perez, Prince, Satcher and Weldon, and non-defendant Director Anne Mulcahy. The director defendants currently serving on the Board are collectively referred to herein as the "Defendants/Current Board Members," or the "Current Board." Plaintiff did not make a pre-suit demand upon the Current Board because, for the reasons set forth below, such demand would have been futile.

204. Under New Jersey law, demand is futile where the particularized facts pleaded in the Complaint create a reasonable doubt that (1) the directors are disinterested and independent,

or (2), in cases challenging a decision of the board, that the challenged decision was the product of a valid exercise of business judgment.

205. In this case, a majority of the members of the Current Board are not disinterested with respect to the matters raised in this Complaint because (a) their knowing decision to permit J&J to pursue multiple unlawful enterprises was not the product of a valid exercise of business judgment, and (b) each of them faces a substantial threat of personal liability with respect to one or more of these matters.

206. Directors of a New Jersey corporation have a fiduciary duty to act loyally and in good faith to oversee its business and affairs and to assure that effective policies, procedures and systems are in place to prevent, and to detect and promptly terminate, unlawful business practices. A New Jersey corporate director breaches the duty of loyalty and good faith by failing to attempt to do so, and by knowingly permitting management to pursue unlawful business practices and strategies. As a fiduciary, each director must in good faith bring to bear all of his or her knowledge, skill, experience and expertise in the fulfillment of the duties of attention and fidelity to the lawful best interests of the corporation.

207. Pursuant to J&J's Principles of Corporate Governance, all of the Company's directors were "well supported by accurate and timely information" and were provided with "sufficient time and resources" to fully attend to all of their crucial oversight responsibilities. Directors have "unrestricted . . . full and free access to officers and employees of the Company." Furthermore, the "Board and each Committee has the authority to engage independent legal, financial or other advisors as it may deem necessary, without consulting or obtaining the approval of any officer of the Company in advance." The Company maintains a "comprehensive orientation program for all new non-employee directors," which includes "extensive written

materials and . . . one-on-one sessions with members of senior management" regarding key oversight topics, including "legal issues, compliance programs and business conduct" matters. Therefore, upon joining the Board, all of the non-employee members of the Current Board were comprehensively briefed on the Company's history of unlawful business practices and the ineffectiveness of the Company's compliance programs to prevent such practices, and during their service on the Board, all of the non-employee members of the Current Board received accurate and timely reports of all compliance issues, unlawful business practices, and investigations and inquiries, and had at their disposal all of the resources necessary to exercise effective oversight and to require that management root out and terminate unlawful business practices occurring at the Company.

208. Through their service on key board committees, the non-employee members of the Current Board (other than Mulcahy who joined the Board in October 2009 and as of the Company's 2010 Proxy Statement was not a member of any committee, and who is not named as a defendant herein) also were directly responsible for crucial front-line oversight responsibilities in the areas of internal controls, legal and regulatory compliance, corporate citizenship, medical risk management affecting patient safety, and corporate governance/board effectiveness. Service on these key committees necessarily exposed these directors to knowledge of the individual instances, and overall pattern, of unlawful business practices reflected in this Complaint, as well as to knowledge of the Board's consistent ineffectiveness in assuring management's prevention of such unlawful business practices.

209. The Company's Audit Committee was responsible at all relevant times for being the Board's front line in the oversight of "Policies and Procedures Addressing Legal and Ethical Concerns," including the "monitoring" of all compliance programs, and reports from the

Company's internal audit function concerning "management improprieties." The Audit Committee was required to report regularly to the full board concerning its meetings and discussions and to review with the full Board all "significant issues and concerns" arising at its meetings. Therefore, the members of the Audit Committee received regular reports both of compliance program activities and of unlawful and unethical business practices, with respect to the Company and all of its operating subsidiaries, and reported these matters to the full Board. From 1997 to 2009, the Audit Committee met over 80 times. Of the Defendants/Current Board Members, four (4) have served on the Audit Committee: Defendant Coleman since 2004, Defendant Cullen since at least 1997, Defendant Langbo from at least 1997 to 2003, and Defendant Mullin since 2000.

210. The Company's Nominating & Corporate Governance Committee was created in April 1998 and was responsible at all relevant times for "overseeing matters of corporate governance," including the evaluation of the performance and practices of the Board, its committees, and the Chief Executive. Its responsibilities include the assessment of the effectiveness of each committee, recommending to the full Board any required changes in committee charters and membership, recommending the annual process for board and committee evaluation, overseeing that process, and regularly reporting to the full Board concerning issues and concerns arising during its meetings. Therefore, the members of the Nominating & Corporate Governance Committee were regularly confronted with considering the consistent ineffectiveness of the Audit Committee and the other Board committees, as well as the Board as a whole in providing effective oversight of management, particularly with respect to assuring management's prevention of unethical and unlawful business practices. And, the Nominating & Corporate Governance Committee regularly reported these matters to the full Board. From 1998

through 2009, the Nominating & Corporate Governance Committee met 49 times. Of the Defendants/Current Board Members, four (4) have served on the Nominating & Corporate Governance Committee: Defendant Cullen since 2004, Defendant Langbo since 2004, Defendant Mullin from 2000 to 2005, and Defendant Prince since 2007.

211. The Company's Public Policy Advisory Committee has at all relevant times consisted both of directors and senior executive officers of the Company, including the General Counsel and senior executives in charge of government and regulatory affairs. The Committee's purpose includes reviewing and advising the Board on governmental and regulatory affairs involving public health issues. Therefore, the director members of the Public Policy Advisory Committee were regularly apprised by the General Counsel and other senior executives of the Company of all regulatory affairs and compliance matters affecting the Company and its operating subsidiaries' relationships with their principal regulators including the FDA and federal and state health care law enforcement authorities, and regularly reported to the full Board concerning significant issues and concerns arising at the committee's meetings. The Public Policy Advisory Committee has existed at least since 1997. Of the Defendants/Current Board Members, four (4) have served on the Public Policy Advisory Committee: Defendant Lindquist since 2004, Defendant Mullin since 2006, Defendant Perez since 2008, and Defendant Satcher since 2003.

212. The Company's Science and Technology Advisory Committee has at all relevant times consisted of both directors and one or more senior scientific or medical officers of the Company. Historically, all directors serving on this committee have had a background of expertise in medical and biological science issues, and due to their background, have expertise in

matters of science, medicine, clinical trial development and conduct, and scientific and medical ethics.

213. Coleman, Johns and Satcher, members of the Science & Technology Advisory Committee, had special expertise and experience relevant to the various schemes detailed herein. Since August 2002, Coleman has served as the President of the University of Michigan with technical expertise in the area of the biochemistry of cancer. Directly relevant to Coleman's knowledge of the facts alleged herein is the fact that one of the members of the 2005 Special Advisory Panel (described above) related to J&J's blockbuster drug, Natrecor, was Dr. Bertram Pitt, a professor at the University of Michigan working under Defendant Coleman at the time. As detailed herein, the purpose of the 2005 Special Advisory Board was, *inter alia*, to examine the safe and effective use of Natrecor in out-patient settings, and to determine whether J&J should conduct more expansive clinical testing on the drug. Both in her capacity as a director of J&J and as the President of the University of Michigan where Dr. Pitt worked, Defendant Coleman was aware of the determination of the Panel, *inter alia*, that Natrecor should not be used out-patient, and that J&J should undertake more expansive clinical trials regarding the drug.

214. Johns has been a member of the Science & Technology Advisory Committee since 2006. Johns served as Executive Vice President for Health Sciences at Emory University from 1996 through October 2007. His background is as an ear, nose and throat surgeon, with expertise in head and neck cancer surgery. In his capacity as Executive Vice President for Health Sciences at Emory University, Johns was heavily engaged in the issue of off-label promotion and marketing because of his responsibility for directing the school's policies in these critical areas. In addition, Emory University Medical School was a major player in the field of

vascular stents. Johns likewise played a critical role in determining whether to allow off-label use of stents and drugs by Emory physicians.

215. Satcher was the Director of Primary Care at the Morehouse School of Medicine from 2002 to 2004. He served as interim President of the Morehouse School of Medicine from 2004 until 2006. He established the Satcher Health Leadership Institute at Morehouse in 2006. Satcher is a former Surgeon General of the United States. In these capacities, Satcher was knowledgeable about and actively involved in healthcare policy outside of J&J and was fully aware of the regulations governing and risks inherent in off-label promotion and marketing of drugs by pharmaceutical companies.

216. Members of the Science and Technology Advisory Committee have served concurrently on the Public Policy Advisory Committee, thus leveraging their scientific expertise to enhance the Board's understanding of the medical science and scientific/medical ethics aspect of the Public Policy Advisory Committee's governmental and regulatory affairs oversight function. The purpose of the Science and Technology Advisory Committee is to review and advise the full Board regarding matters of science, medicine and technology relevant to the operation of the Company's business, including matters of product development, clinical research, pharmacovigilance, and the interface between the Company's scientific activities and the scientific and prescriber community.

217. Therefore, the director members of the Science and Technology Advisory Committee received regular reports from scientific officers of the Company concerning such matters, including the unlawful and unethical business practices and strategies set forth in this Complaint, and regularly reported to the full Board regarding significant issues and concerns that arise at the committee's meetings. The Science & Technology Advisory Committee has existed

at least since 1997. Of the Defendants/Current Board Members, four (4) have served on the Science and Technology Advisory Committee: Defendant Coleman since 2004; Defendant Johns since 2006; Defendant Lindquist since 2004; and Defendant Satcher since 2003.

218. Each of the Director Defendants, including each of the members of the Current Board, knew that as directors of J&J, it was their fiduciary duty and responsibility to oversee management to assure that it acted effectively to prevent unlawful and unethical business practices, and to promptly cause the termination of any existing unlawful and unethical business practices. They also knew that it was a violation of their fiduciary duty of loyalty and good faith to permit the continuation of any such unlawful and unethical business practices, once they became aware of them. As alleged with particularity below, however, they were aware at all relevant times of the unlawful and unethical business practices alleged herein, yet permitted them to be continued, year after year, thus committing knowing breaches of their fiduciary duty of loyalty and good faith.

219. As alleged in detail below, at all relevant times during each of their tenures on the Board, as a result of their service on the Board and on the committees described above, their knowledge and expertise as alleged herein, the receipt by the Board and those committees of regular, complete and accurate reports, the sustained and systematic nature of the wrongdoing over multiple years and across multiple product lines, and as reflected in the Company's disclosures signed by the Director Defendants as specified above, the Defendants/Current Board Members**,** were aware of the unlawful business practices comprising the Topamax Off-Label Promotion Scheme, the Omnicare Kickback Scheme, the Risperdal Off-Label Promotion Scheme, the Natrecor Off-Label Promotion Scheme, the DePuy Kickback Scheme, the Biliary Stent Off-Label Promotion Scheme, and the improperly delayed recall of contaminated OTC

products. These schemes were not the result of a rogue employee or division, but instead reflect a Company-wide business strategy, employed with consistent methods across multiple subsidiaries over extended multi-year periods of time, to maximize sales through off-label promotion and the payment to health care providers and pharmacy benefit managers of kickbacks and inducements, and to avoid or delay any action that could hurt sales and profits regardless of risks to patients and consumers. Thus, the Company, as a de facto matter of policy, manifested over and over again in the various schemes alleged herein, consistently elevated revenues and profits over compliance with laws and regulations designed to protect patient health, including FDA pre-marketing approval requirements for drugs and medical devices, FDA labeling requirements requiring full and adequate warnings of risks posed by specific drugs and devices, and federal statutory law designed to keep the professional decisions of health care providers free of commercial influences, despite the expert knowledge of Company Senior Management and members of the Board that as a result, patients would inevitably be harmed. This strategy was well known to J&J's senior management and its Board, and was knowingly pursued despite their knowledge of its illegality and the inevitable harm to patients. As demonstrated herein, this unlawful and unethical strategy continued even after multiple enforcement investigations were commenced by federal and state regulators and law enforcement authorities, with the knowledge of the Director Defendants that it exposed the Company to criminal prosecution, significant civil and criminal penalties, and the potentially devastating exclusion of Company products from reimbursement under federal health care programs. The Board and J&J management knowingly made a calculated bet that any legal consequences would be insignificant when compared to the increased sales, profits, and cash flows that were expected to result from their unlawful strategy and practices. By knowingly

permitting this strategy to continue, the Director Defendants, including the Defendants/Current Board Members, adopted it as Company policy, and committed a sustained and systematic failure of compliance oversight in breach of their fiduciary duty of loyalty and good faith.

220. The following subparagraphs set forth, year by year beginning in 2002, the pattern of pervasive unlawful business practices occurring at the Company and the Defendants/Current Board Members knowledge thereof.

a. **2002.**

Unlawful Business Practices

(i) The Risperdal Off-Label Promotion Scheme, including promotion of Risperdal for use in elderly patients suffering from dementia or exhibiting hostility. The Risperdal Off-Label Promotion Scheme was occurring despite the FDA's January 5, 1999 notice of violation letter to J&J's Janssen Research Foundation, which specifically notified J&J that such promotion was outside the approved indications for Risperdal and that J&J's Risperdal promotional materials were false and misleading due to unsubstantiated safety, efficacy, comparative, and quality of life claims and lack of fair balance; (ii) the Topamax Off-Label Promotion Scheme; (iii) the Biliary Stent Off-Label Promotion Scheme; (iv) the Omnicare Kickback Scheme; and, (v) initiation of the DePuy Kickback Scheme.

Defendants'/Current Board Members' Knowledge of Wrongdoing

During 2002, Defendants/Current Board members Cullen and Langbo were members of the Board and the Audit Committee, and Defendant/Current Board member Mullin was a member of the Board and of both the Audit committee and the Nominating and Corporate Governance Committee. As such, Cullen, Langbo and Mullin were each aware of all of

the schemes identified immediately above occurring in 2002 as a result of regular reporting on compliance matters and unlawful business practices to the Audit Committee, as alleged above in paragraph 209. Additionally, Defendant Mullin, as a result of his specific duty and responsibility, as a member of the Nominating and Corporate Governance Committee, to consider and evaluate on a regular basis the effectiveness of the Board and its committees in providing compliance oversight, was aware that the Board was failing to take action to exercise appropriate compliance oversight, despite its knowledge of all of the unlawful schemes identified above. Further, as a result of the Nominating and Corporate Governance Committee's reports to the Full Board, all as alleged above in paragraph 209, Defendants/Current Board members Cullen and Langbo were also aware that the Board was failing to take action to exercise appropriate compliance oversight despite its knowledge of all of the unlawful schemes identified above. Thus, Defendants/Current Board members Cullen, Langbo, and Mullin were each aware that they were breaching their fiduciary duties as directors during 2002.

b. **2003.**

Unlawful Business Practices

(i) the Risperdal Off-Label Promotion Scheme, as described above, continued; (ii) the Topamax Off-Label Promotion Scheme continued; (iii) the Biliary Stent Off-Label Promotion Scheme continued; (iv) the Omnicare Kickback Scheme continued; (v) the DePuy Kickback Scheme continued; and, (vi) J&J's adoption and expansion of the off-label promotion of Natrecor following its April 2003 acquisition of Scios. Company Form 10-K disclosures, signed by all persons then serving as J&J directors, show that federal authorities had begun to investigate the Company and its subsidiaries for drug

marketing violations. Specifically, in July 2003, J&J subsidiary Centocor received a request that it voluntarily provide documents and information to the criminal division of the U.S. Attorney's Office, District of New Jersey, in connection with its investigation into various Centocor marketing practices. In December 2003, J&J subsidiary Ortho-McNeil received a subpoena from the U.S. attorney in Boston seeking documents related to the marketing of Topamax for unapproved uses.

Defendants'/Current Board Members' Knowledge of Wrongdoing

(vii) During 2003, Defendants/Current Board members Cullen and Langbo were members of the Board and the Audit Committee. Defendant/Current Board member Mullin was a member of the Board and of both the Audit committee and the Nominating and Corporate Governance Committee. Defendant/Current Board member Satcher was a member of the Board and of both the Public Policy Advisory Committee and the Science and Technology Advisory Committee. Each of these Defendants/Current Board members was aware of all of the schemes identified immediately above occurring in 2003 as a result of regular reporting on compliance matters and unlawful business practices to the Audit Committee, and the Audit Committee's reporting of such matters to the full Board, as alleged above in paragraph 209. Additionally, as a member of the Public Policy Advisory Committee, Defendant/Current Board member Satcher was aware of such matters to the extent they implicated government and regulatory affairs and, to the extent they implicated matters of scientific and medical ethics, Satcher was aware of them as a member of the Science and Technology Advisory Committee. Each of the schemes identified above, were reported to these Board Committees, as alleged above in paragraphs 211 and 216; (viii) Moreover, as alleged in detail above, the Company's

adoption and expansion of Scios's off-label promotion of Natrecor was known to and approved by the Board, including by Defendants/Current Board Members Cullen, Langbo, Mullin, and Satcher, as a result of the Board's in-depth consideration and approval of the Company's acquisition of Scios following comprehensive due diligence. Additionally, with respect to the governmental investigations disclosed in the Company's 10-K filings, which are identified above, the signatures of the Defendants/Current Board members then serving on the Board evidence their knowledge of such matters; (ix) Finally, Defendant Mullin, as a result of his duty and responsibility as a member of the Nominating and Corporate Governance Committee, to specifically consider and evaluate the effectiveness of the Board and its Committees in providing compliance oversight, was aware that the Board was failing to take action to exercise appropriate compliance oversight despite its knowledge of all of the schemes and wrongdoing identified above. As a result of the Nominating and Corporate Governance Committee's reports to the full Board, all as alleged above in paragraph 210 Defendants/Current Board members Cullen, Langbo, and Satcher were also aware that the Board was failing to take action to exercise appropriate compliance oversight despite its knowledge of all of these matters. Thus, Defendants/ Current Board members Cullen, Langbo, Mullin, and Satcher were each aware that they were breaching their fiduciary duties as directors during 2003.

c. **2004.**

Unlawful Business Practices

(i) the Risperdal Off-Label Promotion Scheme, as described above continued; (ii) the Topamax Off-Label Promotion Scheme continued, despite the Company's receipt, in December 2003, of a federal subpoena specifically concerning off-label promotion of

Topamax, and an FDA Warning Letter dated, September 15, 2004, copied to Board Chairman William Weldon, concerning false and misleading Topamax promotional materials that failed to warn of serious health risks; (iii) the Biliary Stent Off-Label Promotion Scheme continued; (iv) the Omnicare Kickback Scheme continued; and (v) the DePuy Kickback Scheme continued; and, (vi) the Natrecor Off-Label Promotion Scheme continued.

Defendants'/Current Board Members' Knowledge of Wrongdoing

(vii) Company 10-K disclosures, signed by all persons then serving as J&J directors, show that all Board Members knew that federal authorities were continuing their investigation of the Company and its subsidiaries for drug marketing violations, and state law enforcement authorities were also beginning to investigate such violations. Specifically, in January, 2004, the Office of Inspector General for the U.S. Office of Personnel Management asked J&J for documents related to payments made to doctors in connection with the sales, marketing and clinical trials for Risperdal. On July 27, 2004, the Company received a letter request from the New York State Attorney General's Office for documents pertaining to marketing, off-label sales and clinical trials for Topamax, Risperdal, Procrit, Reminyl, Remicade and Aciphex. In September 2004, J&J subsidiary Ortho Biotech Inc. received a subpoena from the U.S. Office of Inspector General's Denver, Colorado field office seeking documents directed to the sales and marketing of Procrit from 1997 forward, as well as to dealings with U.S. Oncology Inc., a healthcare services network for oncologists; (viii) The Company's 10-K disclosures also reflected the ongoing nature of previously disclosed investigations. Additionally, all Directors were aware of increased enforcement trends with respect to Pharmaceutical

marketing laws, as evidenced by the following statement in J&J's fiscal year 2004 Form 10-K (signed by each member of the Board at that time): " [S]ales and marketing practices in the health care industry have come under increased scrutiny by government agencies and state attorney generals and resulting investigations and prosecutions carry the risk of significant civil and criminal penalties." (ix) During 2004, Defendants/Current Board members Coleman, Cullen and Mullin were members of the Board and the Audit Committee, Mullin and Cullen were also members of the Nominating and Corporate Governance Committee, Langbo was a member of the Board and the Nominating and Corporate Governance Committee, Coleman was also a member of the Science and Technology Advisory Committee, and Satcher and Lindquist were members of the Board and of both the Public Policy Advisory Committee and the Science and Technology Advisory Committee. Each of these Defendants/Current Board members was aware of each of the unlawful schemes and wrongdoing identified above as a result of regular reporting on compliance matters and unlawful business practices to the Audit Committee, and the Audit Committee's reporting of such matters to the full Board, as alleged above in paragraph 209. Additionally, as members of the Public Policy Advisory Committee, Defendants/Current Board members Satcher and Lindquist were aware of such matters to the extent they implicated government and regulatory affairs, and Satcher, Lindquist, and Coleman were aware of such matters to the extent they implicated matters of scientific and medical ethics as members of the Science and Technology Advisory Committee. Each of the schemes and wrongdoing identified above were reported to these Committees, as alleged above in paragraphs 211 and 216. Additionally, with respect to the governmental investigations disclosed in the Company's 10-K filings identified

above, the signatures of the Defendants/Current Board members then serving on the Board evidence their knowledge of such matters. Defendants/Current Board members Mullin, Langbo and Cullen, as members of the Nominating and Corporate Governance Committee, were specifically charged with reviewing and evaluating the effectiveness of the Board and its Committees in providing compliance oversight, were thus aware that the Board was failing to take action to exercise appropriate compliance oversight despite its knowledge of all of the matters identified above. Further, as a result of the Nominating and Corporate Governance Committee's regular reports to the Full Board, all as alleged above in paragraph 210, Defendants/Current Board members Coleman, Lindquist and Satcher were also aware that the board was failing to take action to exercise appropriate compliance oversight despite its knowledge of all of the schemes and wrongdoing identified above. Thus, each of Defendants/Current Board members Cullen, Langbo, Mullin, Lindquist, Coleman and Satcher were aware that they were breaching their fiduciary duties as directors during 2004**.**

d. **2005.**

Unlawful Business Practices

(i) the Risperdal Off-Label Promotion Scheme, as described above (2002) continued; (ii) the Topamax Off-Label Promotion Scheme, as described above, continued; (iii) the Biliary Stent Off-Label Promotion Scheme; (iv) the DePuy Kickback Scheme continued, despite receipt of a federal subpoena in March 2005 concerning the relationships between DePuy and surgeons or surgeons-in-training involved in hip and knee replacement and reconstructive surgery; and, (v) the Natrecor Off-Label Promotion Scheme continued.

Defendants'/Current Board Members' Knowledge of Wrongdoing

(vi) Company Form 10-K disclosures, signed by all persons then serving as J&J directors, show that federal authorities were continuing their investigation of the Company and its subsidiaries for drug and medical device marketing violations. In March 2005, J&J's Depuy subsidiary received a subpoena from the United Sates Attorney for the District of New Jersey seeking documents relating to contractual relationships between DePuy and surgeons or surgeons-in-training involved in hip and knee replacement and reconstructive surgery. In July 2005, the Company's Scios subsidiary received a subpoena from the United States Attorney's Office for the District of Massachusetts seeking documents relating to the sales and marketing of Natrecor. In September 2005, the Company received a subpoena from the U.S. Attorney's Office, District of Massachusetts, seeking documents related to sales and marketing of eight drugs to Omnicare, Inc. Finally, in November 2005 J&J's Janssen unit received a subpoena from the U.S. Attorney's Office in Philadelphia in seeking information about the marketing and adverse side effects of Risperdal; (vii) The Form 10-K disclosures also reflected the ongoing nature of previously disclosed investigations. Additionally, J&J's Fiscal year 2005 Form 10-K (signed by each member of the Board at that time) indicated the directors' awareness that the increased scrutiny by federal and state law enforcement authorities was expanding beyond sales and marketing practices, as evidenced by the following statement: "[S]ales, marketing and other business practices in the health care industry have come under increased scrutiny by government agencies and state attorney generals and resulting investigations and prosecutions carry the risk of significant civil and criminal penalties." (viii) During 2005, Defendant/Current Board member Johns was a member of the Board, Coleman, Cullen and Mullin were members of the Board and the Audit Committee,

Mullin and Cullen were also members of the Nominating and Corporate Governance Committee, Langbo was a member of the Board and the Nominating and Corporate Governance Committee, Coleman was also a member of the Science and Technology Advisory Committee, and Satcher and Lindquist were members of the Board and of both the Public Policy Advisory Committee and the Science and Technology Advisory Committee. As such, each of these Defendant/Current Board members were aware of each of the schemes and unlawful business practices identified above as a result of regular reporting on compliance matters and unlawful business practices to the Audit Committee, and the Audit Committee's reporting of such matters to the full Board, as alleged above in paragraph 209. Additionally, as members of the Public Policy Advisory Committee Satcher and Lindquist were aware of such matters to the extent they implicated government and regulatory affairs, and Satcher, Lindquist, and Coleman were aware of such matters to the extent they implicated matters of scientific and medical ethics as members of the Science and Technology Advisory Committee. The schemes and unlawful business practices identified above were reported to these Committees, as alleged above in paragraphs 211 and 216. Additionally, with respect to the governmental investigations, disclosed in the Company's 10-K filings as noted above, the signatures of the Defendants/Current Board members then serving on the Board evidence their knowledge of such matters. Defendants/ Current Board members Mullin, Langbo and Cullen, as members of the Nominating and Corporate Governance Committee were specifically charged with reviewing and evaluating the effectiveness of the Board and its Committees in providing compliance oversight, were aware that the Board was failing to take action to exercise appropriate compliance oversight despite its knowledge of each of

the schemes and unlawful business practices identified above. Further, as a result of the Nominating and Corporate Governance Committee's reports to the Full Board, all as alleged above in paragraph 210, Johns, Coleman, Lindquist and Satcher were also aware that the Board was failing to take action to exercise appropriate compliance oversight despite its knowledge of all of these matters. Thus, each of Defendants/ Current Board members Johns, Cullen, Langbo, Mullin, Lindquist, Coleman and Satcher were aware that they were breaching their fiduciary duties as directors during 2005.

e. **2006.**

Unlawful Business Practices

(i) the Risperdal Off-Label Promotion Scheme as described above continued; In addition, in January 2006, the Company received a request for information from the Attorney General of the State of Texas regarding the sales and marketing of Risperdal. In September, 2006, J&J's Janssen unit received a subpoena from the California Attorney General's office seeking documents on sales and marketing and side effects of Risperdal; and the Attorneys General of five states and the Office of General Counsel of Pennsylvania filed actions seeking reimbursement of Medicaid or other public funds for Risperdal prescriptions written for off-label use, compensation for treating their citizens for alleged adverse reactions to Risperdal, civil fines or penalties, punitive damages, or other relief, and the Attorney General of Texas joined a qui tam action in that state seeking similar relief. The Form 10-K disclosures also reflected the ongoing nature of previously disclosed investigations; (ii) the Topamax Off-Label Promotion Scheme, as described above, continued. In addition, in June 2006 the Company received an additional subpoena from the United States Attorneys' Office in Boston for documents

relating to the off-label marketing of Topamax; (iii) the Biliary Stent Off-Label Promotion Scheme continued; and, (iv) the DePuy Kickback Scheme, as described above, continued; Company 10-K disclosures, signed by all persons then serving as J&J directors, show that federal authorities were continuing their investigation of the Company and its subsidiaries for drug and medical device marketing violations, and state law enforcement officials escalated their investigations and enforcement activities directed at the Company's unlawful and unethical business activities.

Defendants'/Current Board Members' Knowledge of Wrongdoing

(v) During 2006 Defendants/Current Board members Coleman, Cullen, Johns, Langbo, Lindquist, Mullin, Prince, and Satcher were members of the Board, Coleman, Cullen, and Mullin were members of the Audit Committee, Lindquist, Mullin, and Satcher were members of the Public Policy Advisory Committee, Coleman, Johns, Lindquist, and Satcher were members of the Science and Technology Advisory Committee, and Cullen and Langbo were members of the Nominating and Corporate Governance Committee. All of them were aware of each of the schemes and unlawful business practices identified above as a result of regular reporting on compliance matters and unlawful business practices to the Audit Committee, and the Audit Committee's reporting of such matters to the full Board, as alleged above in paragraph 209. Additionally, as members of the Public Policy Advisory Committee, Lindquist, Mullin, and Satcher were aware of such matters to the extent they implicated government and regulatory affairs and Coleman, Johns, Lindquist, and Satcher were aware of such matters to the extent they implicated matters of scientific and medical ethics as members of the Science and Technology Advisory Committee. Each of the schemes and unlawful business practices identified

above were reported to such Committees, and all of the other Defendants/Current Board members on the Board at this time were aware of them because such Committees reported such matters to the full Board, as alleged above in paragraphs 211 and 216**;** (vi) Additionally, with respect to the governmental investigations and enforcement actions, disclosed in the Company's Form 10-K filings as noted above, the signatures of the Defendants/Current Board members then serving on the Board evidence their knowledge of such matters. Defendants/Current Board members Langbo and Cullen, as members of the Nominating and Corporate Governance Committee specifically responsible for reviewing and evaluating the effectiveness of the Board and its Committees in providing compliance oversight, were aware that the Board was failing to take action to exercise appropriate compliance oversight despite its knowledge of all of these matters, and as a result of the Nominating and Corporate Governance Committee's reports to the Full Board, all as alleged above in paragraph 210, all of the other Defendants/Current Board members on the Board at this time also knew this fact. Thus, Defendants/Current Board members Coleman, Cullen, Johns, Langbo, Lindquist, Mullin, Prince, and Satcher were each aware that they were breaching their fiduciary duties as directors during 2006.

f. **2007.**

Unlawful Business Practices

(i) the Risperdal Off-Label Promotion Scheme, as described above, continues. In addition, in March, 2007, the Company received a subpoena from the U.S. Attorney's Office in Philadelphia concerning sales and marketing of Risperdal and the Company's supervision of the subsidiary selling Risperdal; (ii) the Topamax Off-Label Promotion Scheme, as described above, continues. In addition, in March 2007 the Company

received a subpoena from the U.S. Attorney's Office in Boston concerning sales and marketing of Topamax and the Company's supervision of the subsidiary selling Topamax; (iii) the Biliary Stent Off-Label Promotion Scheme continues; and (iv) false and misleading promotion of Natrecor , as described above, continues. In addition, in March 2007 the Company received a subpoena from the U.S. Attorney's Office in San Francisco concerning the sale and marketing of Natrecor and the Company's supervision of the subsidiary selling Natrecor. In addition, the Company failed to disclose appropriate indication and patient risk information in violation of FDA reminder advertisement regulations (FDA letter dated November 6, 2007 to J&J's Scios). The Company's Form 10-K disclosures, signed by all persons then serving as J&J directors, show that federal authorities were escalating their investigation of the Company and its subsidiaries for drug and medical device marketing violations, and state enforcement activity against the Company had expanded substantially; (v) Other: In May 2007, the New York State Attorney General issued a subpoena seeking information relating to the marketing and safety of Procrit. In September 2007, the Company was forced to pay $84.7 million to settle charges by the United States' Attorney's Office for the District of New Jersey that its DePuy subsidiary paid kickbacks to orthopedic surgeons to induce them to use DePuy products, and DePuy was forced to plead guilty to criminal violation of the federal anti-kickback statute and to enter into a deferred prosecution agreement and a corporate integrity agreement. In November 2007, the Attorney General of the Commonwealth of Massachusetts issued a civil investigative demand seeking information regarding financial relationships between a number of Massachusetts-based orthopedic surgeons and providers and DePuy. By year end, the attorney generals of

several states indicated a potential interest in pursuing litigation similar to that commenced by Pennsylvania and five other states with respect to false claims and damages caused by the off-label promotion of Risperdal. The 10-K disclosures also reflected the ongoing nature of previously disclosed investigations.

Defendants'/Current Board Members' Knowledge of Wrongdoing

(vi) During 2007, Defendants/Current Board members Coleman, Cullen, Johns, Langbo, Lindquist, Mullin, Perez, Prince, and Satcher were members of the board, Coleman, Cullen, and Mullin were members of the Audit Committee, Lindquist, Mullin, Perez and Satcher were members of the Public Policy Advisory Committee, Coleman, Johns, Lindquist, and Satcher were members of the Science and Technology Advisory Committee, and Cullen, Langbo and Prince were members of the Nominating and Corporate Governance Committee. As such, all of them were aware of each of the schemes and unlawful business practice identified above as a result of regular reporting on compliance matters and unlawful business practices to the Audit Committee, and the Audit Committee's reporting of such matters to the full Board, as alleged above in paragraph 209. Additionally, Lindquist, Mullin, Perez and Satcher, as members of the Public Policy Advisory Committee, were each aware of such matters to the extent they implicated government and regulatory affairs, and Coleman, Johns, Lindquist, and Satcher were aware of such matters to the extent they implicated matters of scientific and medical ethics as members of the Science and Technology Advisory Committee. The schemes and unlawful business practices identified above, were reported to these Committees, and all of the other Defendants/Current Board members on the Board at this time were aware of the schemes and unlawful business practices identified above

because these Committees reported such matters to the full Board, all as alleged above in paragraphs 211 and 216; (vii) Additionally, with respect to the governmental investigations and enforcement actions disclosed in the Company's 10-K filings as noted above, the signatures of the Defendants/Current Board members then serving on the Board evidences their knowledge of such matters. Defendants/Current Board members Langbo, Prince and Cullen, as members of the Nominating and Corporate Governance Committee charged with specifically reviewing and evaluating, the effectiveness of the Board and its Committees in providing compliance oversight, were aware that the Board was failing to take action to exercise appropriate compliance oversight despite its knowledge of each of the schemes and unlawful business practices identified above. Further, as a result of the Nominating and Corporate Governance Committee's reports to the Full Board, all of the other Defendants/Current Board members on the Board at this time also knew of the schemes and unlawful business practices identified above, all as alleged above in paragraph 210. Thus, each of Defendants/Current Board members Coleman, Cullen, Johns, Langbo, Lindquist, Mullin, Perez, Prince, and Satcher were aware that they were breaching their fiduciary duties as directors during 2007.

g. **2008.**

Unlawful Business Practices

(i) the Risperdal Off-Label Promotion Scheme, as described above, continued. In addition, Company 10-K disclosures, signed by all persons then serving as J&J directors, show that the Company was facing the threat of nationwide liability to more than 40 states in connection with the unlawful off-label promotion of Risperdal. By year end, the Attorneys General of more than 40 states indicated a potential interest in pursuing

litigation similar to that commenced by Pennsylvania and eight other states with respect to false claims and damages caused by the off-label promotion of Risperdal; (ii) the Topamax Off-Label Promotion Scheme, as described above, continued; (iii) the Biliary Stent Off-Label Promotion Scheme as described above continued. In addition, in June 2008, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts relating to the marketing of biliary stents by the Company's Cordis subsidiary. Company 10-K disclosures, signed by all persons then serving as J&J directors, show that J&J's pursuit of off-label promotion as a deliberate business strategy, this time in connection with the Biliary Stent Off-Label Promotion Scheme would again expose the Company to adverse investigative and enforcement action; and, (iv) the Company violated cGMP regulations in connection with product odor complaints, as detailed in the Warning Letter dated January 15, 2010, and discussed above.

Defendants'/Current Board Members' Knowledge of Wrongdoing

(v) During 2008, Defendants/Current Board members Coleman, Cullen, Johns, Langbo, Lindquist, Mullin, Perez, Prince, and Satcher were members of the Board, Coleman, Cullen, and Mullin were members of the Audit Committee, Lindquist, Mullin, Perez and Satcher were members of the Public Policy Advisory Committee, Coleman, Johns, Lindquist, and Satcher were members of the Science and Technology Advisory Committee, and Cullen, Langbo and Prince were members of the Nominating and Corporate Governance Committee. Each of these Defendants/Current Board members was aware of all of the schemes and unlawful business practices identified above as a result of regular reporting on compliance matters and unlawful business practices to the

Audit Committee, and the Audit Committee's reporting of such matters to the full Board, as alleged above in paragraph 209. Additionally, Defendants/Current Board members Lindquist, Mullin, Perez and Satcher, as members of the Public Policy Advisory Committee, were aware of such matters to the extent they implicated government and regulatory affairs and Defendants/Current Board members Coleman, Johns, Lindquist, and Satcher were aware of such matters to the extent they implicated matters of scientific and medical ethics as members of the Science and Technology Advisory Committee. Each of the schemes and unlawful business practices identified above was reported to these committees, and all of the other Defendants/Current Board members on the Board at this time were aware of them because these Committees reported such matters to the full Board , as alleged above in paragraphs 211 and 216; (vi) Additionally, with respect to the governmental investigation and state enforcement actions disclosed in the Company's 10-K filings as noted above, the signatures of the Defendants/Current Board members then serving on the Board evidence their knowledge of such matters. Defendants/Current Board members Langbo, Prince and Cullen, as members of the Nominating and Corporate Governance Committee, specifically charged with reviewing and evaluating , the effectiveness of the Board and its Committees in providing compliance oversight, were aware that the Board was failing to take action to exercise appropriate compliance oversight despite its knowledge of each of the schemes and unlawful business practices identified above, and as a result of the Nominating and Corporate Governance Committee's reports to the Full Board, all of the other Defendants/Current Board members on the Board at this time also knew this fact, as alleged above in paragraph 210. Thus, Defendants/Current Board members Coleman, Cullen, Johns, Langbo, Lindquist,

Mullin, Perez, Prince, and Satcher were each aware that they were breaching their fiduciary duties as directors during 2008.

h. **2009.**

Unlawful Business Practices

During 2009, J&J continued to be extensively involved in unlawful activity, including violation of cGMP regulations in connection with product odor complaints, as detailed in the Warning Letter dated January 15, 2010, and discussed above. Company 10-K disclosures, signed by all persons then serving as J&J directors, show that the Company's unlawful business practices relating to drug and medical device marketing and promotion, as well as clinical development, continued to provoke law enforcement investigations and enforcement actions as follows: (i) in April 2009, the Company received a HIPPA subpoena from the U.S. Attorney's Office for the District of Massachusetts (Boston) seeking information regarding the Company's financial relationship with several psychiatrists; (ii) in May 2009, the New Jersey Attorney General issued a subpoena to DePuy Orthopaedics, Inc., seeking information regarding the financial interest of clinical investigators who performed clinical studies for DePuy Orthopaedics, Inc. and DePuy Spine, Inc.; and (iii) The 10-K disclosures also reflected the ongoing nature of previously disclosed multiple investigations and enforcement activities at the federal and state level.

Defendants'/Current Board Members' Knowledge of Wrongdoing

(iv) During 2009, Defendants/Current Board members Coleman, Cullen, Johns, Langbo, Lindquist, Mullin, Perez, Prince, and Satcher were members of the Board, Coleman, Cullen, and Mullin were members of the Audit Committee, Lindquist, Mullin, Perez and

Satcher were members of the Public Policy Advisory Committee, Coleman, Johns, Lindquist, and Satcher were members of the Science and Technology Advisory Committee, and Cullen, Langbo and Prince were members of the Nominating and Corporate Governance Committee. Each of these Defendants/Current Board members was aware of all of the schemes and unlawful business practices identified above as a result of regular reporting on compliance matters and unlawful business practices to the Audit Committee, and the Audit Committee's reporting of such matters to the full Board, as alleged above in paragraph 209; (v) Additionally, Defendants/Current Board members Lindquist, Mullin, Perez and Satcher, as members of the Public Policy Advisory Committee, were aware of such matters to the extent they implicated government and regulatory affairs and Coleman, Johns, Lindquist, and Satcher were aware of such matters to the extent they implicated matters of scientific and medical ethics as members of the Science and Technology Advisory Committee. The schemes and unlawful business practices identified above , were reported to these Committees, and all of the other Defendants/Current Board Members on the Board at this time were aware of them because these Committees reported such matters to the full Board, as alleged in paragraphs 211 and 216; (vi) Additionally, Defendants/Current Board Members Langbo, Prince and Cullen, as members of the Nominating and Corporate Governance Committee, specifically charged with reviewing and evaluating, the effectiveness of the Board and its Committees in providing compliance oversight, were aware that the Board was failing to take action to exercise appropriate compliance oversight despite its knowledge of all of the schemes and unlawful business practices identified above and as a result of the Nominating and Corporate Governance Committee's reports to the Full Board, all of the

other Defendants/Current Board members on the Board at this time also knew this fact, as alleged in above in paragraph 210. Thus, Defendants/Current Board Members Coleman, Cullen, Johns, Langbo, Lindquist, Mullin, Perez, Prince, and Satcher were each aware that they were breaching their fiduciary duties as directors during 2009.

221. As demonstrated in the immediately preceding paragraph, the Board (including the Defendants/Current Board Members) has knowingly permitted J&J's management to pursue a long-term strategy of unlawful and unethical business practices, characterized by the simultaneous pursuit of multiple off-label promotion and kickback schemes utilizing similar methods and tactics across multiple subsidiaries and business units and involving multiple drugs and medical devices.

222. As Chairman and CEO from 2002 forward, and as Worldwide Chairman of J&J's Pharmaceuticals Group from 1998 to 2002, Defendant/Current Board Member Weldon is responsible for the pervasive pattern of deliberate unlawful conduct reflected in the Topamax Off-Label Promotion Scheme, the Omnicare Kickback Scheme, the Risperdal Off-Label Promotion Scheme, the Natrecor Off-Label Promotion Scheme, the DePuy Kickback Scheme, the Biliary Stent Off-Label Promotion Scheme, and the improperly delayed recall of contaminated OTC products.

223. These multiple illegal schemes cannot be attributed to an anomalous incident of misconduct within the Company or from the acts of a rogue employee or division within the Company. Rather, as alleged herein, serious violations of the drug marketing laws and FDA regulations occurred systematically and pervasively across multiple business units. This pattern of unlawful business practices reflects a decision to embrace a policy of calculated legal violations as the Company's deliberate business strategy, of which Weldon as CEO and as

Worldwide Chairman of J&J's Pharmaceuticals Group necessarily had knowledge. As Worldwide Chairman of J&J's Pharmaceuticals Group beginning in 1998, Weldon embraced, directed, encouraged, and pursued the Topamax Off-Label Promotion Scheme, the Omnicare Kickback Scheme, and the Risperdal Off-Label Promotion Scheme – with the knowledge of the Board – to drive pharmaceutical sales and catapult himself to the position of Chairman of the Board and Chief Executive Officer in 2002. As Chairman and CEO, he continued these schemes, presided over the initiation of the DePuy Kickback Scheme and the Company's acquisition of Scios, which depended substantially on continuation and expansion of Scios's off-label promotion of Natrecor, and continued the Biliary Stent Off-Label Promotion Scheme – by which the Company applied its off-label promotion strategy to its medical devices business segment – through the Company's Cordis subsidiary There is no legitimate "business judgment" involved in Weldon's knowing pursuit of such unlawful business strategies and tactics. His actions constitute a breach of the fiduciary duty of loyalty and good faith as to which Weldon faces a substantial risk of liability, rendering him personally interested and incapable of impartially considering a pre-suit demand.

224. Defendant/Current Board Member Coleman has served on the Board, the Audit Committee and the Science and Technology Advisory Committee since September 2003, and accordingly had all of the knowledge attributed to her in [¶ 220(b)-(h)] above, and with such knowledge, knowingly permitted the Company to continue to pursue its unlawful and unethical business practices and strategies as alleged in such [¶ 220(b)-(h)], thereby breaching her fiduciary duty of loyalty and good faith, with knowledge that she was doing so. Such conduct is not the product of a valid exercise of business judgment, and constitutes a non-exculpable breach of fiduciary duty for which she faces a substantial threat of personal liability.

225. Defendant/Current Board Member Cullen has served on the Board since 1995, on the Audit Committee since 1997, and on the Nominating and Corporate Governance Committee since 2004, and accordingly had all of the knowledge attributed to him in [¶ 220(a)-(h)] above, and with such knowledge, knowingly permitted the Company to continue to pursue its unlawful and unethical business practices and strategies as alleged in such [¶ 220(a)-(h)], thereby breaching his fiduciary duty of loyalty and good faith, with knowledge that he was doing so. Such conduct is not the product of a valid exercise of business judgment, and constitutes a non-exculpable breach of fiduciary duty for which he faces a substantial threat of personal liability.

226. Defendant/Current Board Member Johns has served on the Board since 2005, and on the Science and Technology Advisory Committee since 2006, and accordingly had all of the knowledge attributed to him in [¶ 220(d)-(h)] above, and with such knowledge, knowingly permitted the Company to continue to pursue its unlawful and unethical business practices and strategies as alleged in such [¶ 220(d)-(h)], thereby breaching his fiduciary duty of loyalty and good faith, with knowledge that he was doing so. Such conduct is not the product of a valid exercise of business judgment, and constitutes a non-exculpable breach of fiduciary duty for which he faces a substantial threat of personal liability.

227. Defendant/Current Board Member Langbo has served on the Board since 1991, served on the Audit Committee from at least 1997 to 2003, and has served on the Nominating and Corporate Governance Committee since 2004, and accordingly had all of the knowledge attributed to him in [¶ 220(a)-(h)] above, and with such knowledge, knowingly permitted the Company to continue to pursue its unlawful and unethical business practices and strategies as alleged in such [¶ 220(a)-(h)] , thereby breaching his fiduciary duty of loyalty and good faith, with knowledge that he was doing so. Such conduct is not the product of a valid exercise of

business judgment, and constitutes a non-exculpable breach of fiduciary duty for which he faces a substantial threat of personal liability.

228. Defendant/Current Board Member Lindquist has served on the Board the Public Policy Advisory Committee, and the Science and Technology Advisory Committee since February 2004, and accordingly had all of the knowledge attributed to her in [¶ 220(c)-(h)] above, and with such knowledge, knowingly permitted the Company to continue to pursue its unlawful and unethical business practices and strategies as alleged in such [¶ 220(c)-(h)], thereby breaching her fiduciary duty of loyalty and good faith, with knowledge that she was doing so. Such conduct is not the product of a valid exercise of business judgment, and constitutes a non-exculpable breach of fiduciary duty for which she faces a substantial threat of personal liability.

229. Defendant/Current Board Member Mullin has served on the Board since 1999, on the Audit Committee since 2000, on the Public Policy Advisory Committee since 2006, and on the Nominating and Corporate Governance Committee from 2000 to 2005, and accordingly had all of the knowledge attributed to him in [¶ 220(a)-(h)] above, and with such knowledge, knowingly permitted the Company to continue to pursue its unlawful and unethical business practices and strategies as alleged in such [¶ 220(a)-(h)] thereby breaching his fiduciary duty of loyalty and good faith, with knowledge that he was doing so. Such conduct is not the product of a valid exercise of business judgment, and constitutes a non-exculpable breach of fiduciary duty for which he faces a substantial threat of personal liability.

230. Defendant/Current Board Member Perez has served on the Board since June 2007 and on the Public Policy Advisory Committee since 2008, and accordingly had all of the knowledge attributed to him in [¶ 220(f)-(h)] above, and with such knowledge, knowingly permitted the Company to continue to pursue its unlawful and unethical business practices and

strategies as alleged in such [¶ 220(f)-(h)] , thereby breaching his fiduciary duty of loyalty and good faith, with knowledge that he was doing so. Such conduct is not the product of a valid exercise of business judgment, and constitutes a non-exculpable breach of fiduciary duty for which he faces a substantial threat of personal liability.

231. Defendant/Current Board Member Prince has served on the Board since 2006 and on the Nominating and Corporate Governance Committee since 2007, and accordingly had all of the knowledge attributed to him in [¶ 220(e)-(h)] above, and with such knowledge, knowingly permitted the Company to continue to pursue its unlawful and unethical business practices and strategies as alleged in such [¶ 220(e)-(h)] , thereby breaching his fiduciary duty of loyalty and good faith, with knowledge that he was doing so. Such conduct is not the product of a valid exercise of business judgment, and constitutes a non-exculpable breach of fiduciary duty for which he faces a substantial threat of personal liability.

232. Defendant/Current Board Member Satcher has served on the Board since 2002 and on the Public Policy Advisory Committee and the Science and Technology Advisory Committee since 2003, and accordingly had all of the knowledge attributed to him in [¶ 220(a)-(h)] above, and with such knowledge, knowingly permitted the Company to continue to pursue its unlawful and unethical business practices and strategies as alleged in such [¶ 220(a)-(h)] , thereby breaching his fiduciary duty of loyalty and good faith, with knowledge that he was doing so. Such conduct is not the product of a valid exercise of business judgment, and constitutes a non-exculpable breach of fiduciary duty for which he faces a substantial threat of personal liability.

233. In conclusion, as specifically alleged above:

(a) ten (10) out of a total of eleven (11) current directors of the Company – Weldon, Coleman, Cullen, Johns, Langbo, Lindquist, Mullin, Perez, Prince, and Satcher – face a substantial threat of personal liability with respect to claims in this Action, and the challenged conduct of each of them was not the product of a valid exercise of business judgment; and

(b) seven (7) out of a total of eleven (11) current directors of the Company – Weldon, Coleman, Cullen, Langbo, Lindquist, Mullin, and Satcher--face a substantial threat of personal liability with respect to each of the Risperdal Off-Label Promotion Scheme, the Topamax Off-Label Promotion Scheme, the Biliary Stent Off-Label Promotion Scheme, the Natrecor Off-Label Promotion Scheme, the Omnicare Kickback Scheme, the Depuy Kickback Scheme and the improperly delayed recall of contaminated OTC products.

234. Therefore, a majority of the members of the Current Board are not disinterested for the purposes of a pre-suit demand with respect to the claims set forth in this Complaint. Accordingly, demand is futile and therefore legally excused under New Jersey law.

VI. BREACHES OF FIDUCIARY DUTY BY THEFORMER DIRECTOR DEFENDANTS

235. Director Defendant Jordan served on the Board from 1981 until April 2007. From at least 1997 to 1999, Jordan served on the Audit Committee, from 1999 to 2003, and from 2006 until April 2007, she served on the Nominating and Corporate Governance Committee, and from at least 1997 to 2005, she served on the Public Policy Advisory Committee. Pursuant to the Company's Principles of Corporate Governance, as a director and board committee member, Jordan was "well supported by accurate and timely information" and was provided with

"sufficient time and resources" to fully attend to all of her crucial oversight responsibilities. Therefore, for each of the years from 2002 through 2006, Jordan possessed all of the knowledge attributed to directors and members of the committees on which she served in ¶ 220(a)-(e). With such knowledge, Jordan knowingly permitted the Company to continue to pursue its unlawful and unethical business practices and strategies as alleged in such [¶ 220(a)-(e)], thereby breaching her fiduciary duty of loyalty and good faith, with knowledge that she was doing so.

236. Director Defendant Schacht served on the Board from 1997 to April 28, 2005. He served on the Audit Committee from 1998 to 2005 and on the Nominating and Corporate Governance Committee from 1999 to 2004. Pursuant to the Company's Principles of Corporate Governance, as a director and board committee member, Schacht was "well supported by accurate and timely information" and was provided with "sufficient time and resources" to fully attend to all of his crucial oversight responsibilities. Therefore, for each of the years from 1997 through 2005, Schacht possessed all of the knowledge attributed to directors and members of the committees on which he served in ¶ 220(a)-(c). With such knowledge, Schacht knowingly permitted the Company to continue to pursue its unlawful and unethical business practices and strategies as alleged in such [¶ 220(a)-(c)], thereby breaching his fiduciary duty of loyalty and good faith, with knowledge that he was doing so.

237. Director Defendant Reinemund served on the Board from 2003 until April 24, 2008, and served on the Nominating and Corporate Governance Committee from 2004 to 2008. Pursuant to the Company's Principles of Corporate Governance, as a director and board committee member, Reinemund was "well supported by accurate and timely information" and was provided with "sufficient time and resources" to fully attend to all of his crucial oversight responsibilities. Therefore, for each of the years from 2003 through 2007, Schacht possessed all

of the knowledge attributed to directors and members of the committees on which he served in ¶ 220(b)-(f). With such knowledge, Schacht knowingly permitted the Company to continue to pursue its unlawful and unethical business practices and strategies as alleged in such [¶ 220(b)-(f)], thereby breaching his fiduciary duty of loyalty and good faith, with knowledge that he was doing so.

238. Director Defendant Darretta served on the Board from 2002 until 2006. Darretta was a management insider, named Chief Financial Officer and appointed to the Executive Committee in 1997. He was appointed Executive Vice President in 2002 and Vice Chairman of the Board in January 2004. As a member of the Company's senior executive management and Executive Committee, Darretta had intimate knowledge of the Company's business strategies and tactics, including the unlawful and unethical business practices alleged herein. Pursuant to the Company's Principles of Corporate Governance, as a director Darretta was "well supported by accurate and timely information" and was provided with "sufficient time and resources" to fully attend to all of his crucial Board oversight responsibilities. For each of the years from 2002 through 2006, comprising his service on the Board, Darretta possessed all of the knowledge attributed to directors in ¶ 220(a)-(e). With such knowledge, Darretta knowingly permitted the Company to continue to pursue its unlawful and unethical business practices and strategies as alleged in such [¶ 220(a)-(e)], thereby breaching his fiduciary duty of loyalty and good faith, with knowledge that he was doing so.

239. Director Defendant Lenehan served on the Board from 2001 until February 1, 2004. Lenehan was a management insider, named in 1993 as Company Group Chairman and worldwide Franchise Chairman for Consumer Pharmaceuticals and a member of the Consumer Group Operating Committee. In 1994, he was promoted to Executive Committee member and

Worldwide Chairman, Consumer Pharmaceuticals & Medical Devices Group. He was Worldwide Chairman of Johnson & Johnson's Medical Devices and Diagnostics Group from 1999 to 2001, when he became Vice Chairman of the Board, a position in which he also had responsibility for the consumer business. He was named to the additional position of President of Johnson & Johnson in 2002. As a member of the Company's senior executive management and Executive Committee, Lenehan had intimate knowledge of the Company's business strategies and tactics, including the unlawful and unethical business practices alleged herein. Pursuant to the Company's Principles of Corporate Governance, as a director Lenehan was "well supported by accurate and timely information" and was provided with "sufficient time and resources" to fully attend to all of his crucial Board oversight responsibilities. For each of the years from 2001 through 2003, comprising his service on the Board, Lenehan possessed all of the knowledge attributed to directors in ¶ 220(a)-(b). With such knowledge, Lenehan knowingly permitted the Company to continue to pursue its unlawful and unethical business practices and strategies as alleged in such [¶ 220(a)-(b)], thereby breaching his fiduciary duty of loyalty and good faith, with knowledge that he was doing so.

240. Director Defendant Wilson served on the Board from 1986 until April, 2003. He served as Vice Chairman of the Board from 1989 until 2002. Wilson was a management insider, appointed Company Group Chairman in 1981, to the Executive Committee in 1983, as Chairman of a Sector Operating Committee in 1985, and as Vice Chairman of the Board of Directors in 1989. He was named Senior Vice Chairman of the Board of Directors in 2001. He assumed expanded responsibilities as Vice Chairman of the Executive Committee in 1994. Wilson also served on the Science and Technology Advisory Committee. As a member of the Company's senior executive management and Executive Committee, Wilson had intimate knowledge of the

Company's business strategies and tactics, including the unlawful and unethical business practices alleged herein. Pursuant to the Company's Principles of Corporate Governance, as a director Wilson was "well supported by accurate and timely information" and was provided with "sufficient time and resources" to fully attend to all of his crucial Board oversight responsibilities. For each of the years from 1997 through 2002, during his service on the Board, Wilson possessed all of the knowledge attributed to directors in ¶ 220(a)-(b). With such knowledge, Wilson knowingly permitted the Company to continue to pursue its unlawful and unethical business practices and strategies as alleged in such [¶ 220(a)-(b)], thereby breaching his fiduciary duty of loyalty and good faith, with knowledge that he was doing so.

VII. BREACHES OF FIDUCIARY DUTY BY THE OFFICER DEFENDANTS

241. As officers of a New Jersey corporation, each of the Officer Defendants Weldon, Poon, Valeriani, Scodari, Torphy, Gorsky and Deyo owed the Company and its shareholders a fiduciary duty of utmost fidelity and absolute good faith, as well as the duty to exercise that degree of care that an ordinarily prudent officer would use under the circumstances. Each officer is duty-bound to bring to bear all of his or her knowledge, skill, experience and expertise in the fulfillment of his or her appointed official duties. Moreover, corporate officers are required to faithfully pursue the lawful best interests and advantage of the corporation. Officers breach their fiduciary duty of loyalty and good faith when they directly, or knowingly cause or permit the corporation and those acting under their authority and supervision to violate the laws applicable to the corporation's business activities.

242. Defendant Weldon has served as Chief Executive Officer of J&J and Chairman of the Executive Committee from April 2002 until the present. As Worldwide Chairman of the

Company's Pharmaceuticals Group and as a member of the Executive Committee from 1998 to April 2002, and later as CEO and Chairman of the Executive Committee, Weldon had knowledge of, and responsibility for, and approved and directed, the promotional and marketing strategies for each of the Company's pharmaceutical products, including, without limitation, Risperdal, Topamax, and Natrecor, including the Risperdal Off-Label Promotion Scheme, the Topamax Off-Label Promotion Scheme, and the Natrecor Off-Label Promotion Scheme, as well as the Omnicare Kickback Scheme, all as alleged herein. Furthermore, as a member of the Executive Committee and as CEO and Chairman of the Executive Committee, Weldon had knowledge of, and responsibility for, and approved and ultimately as CEO directed the use of the Company's off-label promotion strategy in the Biliary Stent Off-Label Promotion Scheme, as well as the kickback strategy employed in the DePuy Kickback Scheme. Finally, as CEO and Chairman of the Executive Committee, Weldon had knowledge of the Company's receipt of OTC product odor complaints and approved and directed the Company's improper failure to complete a timely and adequate investigation of the matters addressed in the January 2010 Warning Letter, as discussed herein. Throughout the period from 1998 to the present, Weldon was fully aware of the unlawful and unethical nature of all of these activities, and nevertheless knowingly approved and directed their execution as consistent with the Company's ongoing and long-standing policy of promoting the broadest possible use and sales of the its pharmaceutical and medical device products, regardless of the applicable law, thus knowingly breaching his fiduciary duty of loyalty and good faith to the Company.

243. Defendant Poon joined the Company in 2000 as a Company Group Chairman in the Pharmaceuticals Group, was named a Member of the Executive Committee and Worldwide Chairman, Pharmaceuticals Group in 2001, and was named Worldwide Chairman, Medicines &

Nutritionals in 2003. In 2007, Poon assumed responsibility for the J&J Development Corporation, the Corporate Office of Science and Technology, the Corporate Office of Information Management, Worldwide Procurement and Worldwide Operations, and was again named Worldwide Chairman, Pharmaceuticals Group in January 2008. Throughout her executive tenure at J&J, Poon had knowledge of, and responsibility for, and approved and directed, the promotional and marketing strategies for each of the Company's pharmaceutical products, including, without limitation, Risperdal, Topamax, and Natrecor, including the Risperdal Off-Label Promotion Scheme, the Topamax Off-Label Promotion Scheme, and the Natrecor Off-Label Promotion Scheme, as well as the Omnicare Kickback Scheme, all as alleged herein. Furthermore, as a member of the Executive Committee, Poon had knowledge of, and responsibility for, and approved and directed the use of the Company's off-label promotion strategy in the Biliary Stent Off-Label Promotion Scheme, as well as the kickback strategy employed in the DePuy Kickback Scheme. Throughout the period from 2000 to the present, Poon was fully aware of the unlawful and unethical nature of all of these activities, and nevertheless knowingly approved and directed their execution as consistent with the Company's ongoing and long-standing policy of promoting the broadest possible use and sales of the its pharmaceutical and medical device products, regardless of the applicable law, thus knowingly breaching her fiduciary duty of loyalty and good faith to the Company.

244. Defendant Nicholas Valeriani ("Valeriani") served as Worldwide Franchise Chairman for the DePuy franchise beginning in 2002, became a member of the Executive Committee in September 2003, assumed responsibility for the company's diagnostics businesses and was named Worldwide Chairman, Diagnostics in the first quarter of 2004, and later in 2004, was named Worldwide Chairman, Cardiovascular Devices and Diagnostics. In 2006, he

assumed responsibility for a newly-created Cardiovascular Devices & Diagnostics Group Operating Committee, which included LifeScan, Inc., Cordis Corporation and Ortho-Clinical Diagnostics, Inc. As reported by the Wall Street Journal on November 16, 2007, Valeriani "split oversight of [J&J's] $20 billion [Medical Devices] division with" Michael Dormer. Throughout the period from 2002 forward, as a result of his senior executive responsibilities and activities relating to J&J's medical devices segment, and from 2003 forward as a result of his membership of the Executive Committee, Valeriani had knowledge of, and responsibility for, and approved and directed, the promotional and marketing strategies for the Company's medical device products, including, without limitation, DePuy products and the Company's biliary stent products, including the DePuy Kickback Scheme and the Biliary Stent Off-Label Promotion Scheme, all as alleged herein. Valeriani was fully aware of the unlawful and unethical nature of all of these activities, and nevertheless knowingly approved and directed their execution, consistent with the Company's ongoing and long-standing policy of promoting the broadest possible use and sales of the its pharmaceutical and medical device products, regardless of the applicable law, thus knowingly breaching his fiduciary duty of loyalty and good faith to the Company.

245. Defendant Joseph Scodari joined J&J in 1999 and in 2001 he was named Company Group Chairman for the Johnson & Johnson North American Pharmaceuticals business, and became a member of the Pharmaceuticals Group Operating Committee. From 2003 to 2005, Mr. Scodari was Company Group Chairman of J&J's Biopharmaceutical Business, and was Worldwide Chairman, Pharmaceuticals Group, and a member of the Executive Committee from March 2005 until March, 2008. Throughout the period from 2000 to his retirement in 2008, Scodari acted as leading deputy to Defendant Poon in the Company's

pharmaceutical segment. Throughout his executive tenure at J&J, Scodari had knowledge of, and responsibility for, and approved and directed, the promotional and marketing strategies for each of the Company's pharmaceutical products, including, without limitation, Risperdal, Topamax, and Natrecor, including the Risperdal Off-Label Promotion Scheme, the Topamax Off-Label Promotion Scheme, and the Natrecor Off-Label Promotion Scheme, as well as the Omnicare Kickback Scheme, all as alleged herein. Furthermore, as a member of the Executive Committee, Scodari had knowledge of, and approved the use of the Company's off-label promotion strategy in the Biliary Stent Off-Label Promotion Scheme, as well as the kickback strategy employed in the DePuy Kickback Scheme. Throughout the period from 2000 to his retirement in 2008, Scodari was fully aware of the unlawful and unethical nature of all of these activities, and nevertheless knowingly approved and/or directed their execution, consistent with the Company's ongoing and long-standing policy of promoting the broadest possible use and sales of the its pharmaceutical and medical device products, regardless of the applicable law, thus knowingly breaching his fiduciary duty of loyalty and good faith to the Company.

246. Defendant Ted Torphy was the Corporate Vice President of Science & Technology, and sat on the Science & Technology Advisory Committee of the Board from 2003 through 2006. Torphy was actively engaged with the members of the Science & Technology Advisory Committee, including helping to set the agenda for Science & Technology Advisory Committee meetings. In that capacity, Torphy actively interfaced with Research and Development components of the Company. Throughout the period from 2003 through 2006, Torphy had knowledge of the promotional and marketing strategies for each of the Company's pharmaceutical products, including, without limitation, Risperdal, Topamax, and Natrecor, including the Risperdal Off-Label Promotion Scheme, the Topamax Off-Label Promotion

Scheme, the Natrecor Off-Label Promotion Scheme, and the Biliary Stent Off-Label Promotion Scheme, as well as the Omnicare Kickback Scheme and the DePuy Kickback Scheme, all as alleged herein. Throughout the period from 2003 through 2006, Torphy was fully aware of the unlawful and unethical nature of all of these activities, and nevertheless knowingly approved and/or acquiesced in their execution, consistent with the Company's ongoing and long-standing policy of promoting the broadest possible use and sales of the its pharmaceutical and medical device products, regardless of the applicable law, thus knowingly breaching his fiduciary duty of loyalty and good faith to the Company.

247. Defendant Alex Gorsky has been J&J's Worldwide Chairman, Medical Devices and Diagnostics Group since September 2009, and a member of Johnson & Johnson's Executive Committee since January 2009. He came to Johnson & Johnson in 2008 after serving as head of Novartis Pharmaceuticals Corporation's North American pharmaceuticals business. Prior to joining Novartis in 2004, Gorsky had served in various management positions at Johnson & Johnson, beginning as a sales representative with Janssen Pharmaceutica Inc in 1988. Over the next 15 years, he advanced through positions of increasing responsibility in sales, marketing and management, and was ultimately named President of Janssen Pharmaceutica Inc. in the U.S. As leader of Janssen's management board, Mr. Gorsky had responsibility for all of its functional areas, including, *inter alia*, marketing, sales and medical affairs. While at J&J's Janssen subsidiary, Gorsky had principal responsibility for the commercialization of Risperdal, including the conceptualization and execution of the Risperdal Off-Label Promotion Scheme. Gorsky thus had knowledge of, and responsibility for, and approved and directed, the Risperdal Off-Label Promotion Scheme. Gorsky was fully aware of the unlawful and unethical nature of the Risperdal Off-Label Promotion Scheme, but nevertheless knowingly approved and directed its

execution, consistent with the Company's ongoing and long-standing policy of promoting the broadest possible use and sales of the its pharmaceutical and medical device products, regardless of the applicable law, thus knowingly breaching his fiduciary duty of loyalty and good faith to the Company.

248. Defendant Russell Deyo became a member of the Executive Committee and Vice President, Administration in 1996 and Vice President, General Counsel and Chief Compliance Officer in April, 2004. From at least 2002 to 2009, Deyo was a management member of the Board's Public Policy Advisory Committee, thus serving as a key advisor to the Board on matters of governmental and regulatory affairs and compliance. As a member of the Executive Committee since 1996 and as General Counsel and Chief Compliance Officer from 2004 forward, Deyo had knowledge of, and responsibility for, and approved, the promotional and marketing strategies for each of the Company's pharmaceutical products, including, without limitation, Risperdal, Topamax, and Natrecor, including the Risperdal Off-Label Promotion Scheme, the Topamax Off-Label Promotion Scheme, and the Natrecor Off-Label Promotion Scheme, and also had knowledge and approved of the use of the Company's off-label promotion strategy in the Biliary Stent Off-Label Promotion Scheme, as well as the kickback strategy employed in the DePuy Kickback Scheme. Finally, as Executive Committee member, General Counsel, and Chief Compliance Officer, Deyo had knowledge of the Company's receipt of OTC product odor complaints and approved and directed the Company's improper failure to complete a timely and adequate investigation of the matters addressed in the January 2010 Warning Letter, as discussed herein. Throughout the period from 1998 to the present, Deyo was fully aware of the unlawful and unethical nature of all of these activities, and nevertheless knowingly approved their execution as consistent with the Company's ongoing and long-standing policy of promoting

the broadest possible use and sales of the its pharmaceutical and medical device products, regardless of the applicable law, thus knowingly breaching his fiduciary duty of loyalty and good faith to the Company.

VIII. DERIVATIVE DAMAGES SUFFERED BY J&J

249. As a result of the Defendants' deliberate breaches of their fiduciary duties in connection with the Omnicare Kickback Scheme, the Risperdal Off-Label Promotion Scheme, the Natrecor Off-Label Promotion Scheme, the Topamax Off-Label Promotion Scheme, the DePuy Kickback Scheme, the Biliary Stent Off-Label Promotion Scheme, and/or the Delayed OTC Scheme (as detailed above), J&J has suffered and will continue to suffer substantial harm.

250. J&J was forced to pay almost $85 million in September 2007 to resolve criminal and civil charges related to the unlawful paying and offering of inducements to orthopedic surgeons to use DePuy hip and knee joint reconstruction and replacement products.

251. Moreover, J&J has incurred substantial costs and expense in responding to multiple federal and state regulatory subpoenas, requests for documents, investigations, and complaints, as well as to *qui tam* complaints, in connection with the Omnicare Kickback Scheme, the Risperdal Off-Label Promotion Scheme, the Natrecor Off-Label Promotion Scheme, the Topamax Off-Label Promotion Scheme, the DePuy Kickback Scheme, the Biliary Stent Off-Label Promotion Scheme, and/or the Delayed OTC Scheme.

252. In addition, Defendants' breaches of their fiduciary duties to the Company have also exposed the Company to substantial injury to its reputation and corporate goodwill, as well as to potential criminal and civil liability.

COUNT I
(Against the Enumerated Directors and Officers for Breach of Fiduciary Duty in connection with the Omnicare Kickback Scheme, the Risperdal Off-Label Promotion Scheme, the Natrecor Off-Label Promotion Scheme, the Topamax Off-Label Promotion Scheme, the DePuy Kickback Scheme, the Biliary Stent Off-Label Promotion Scheme, and the Delayed OTC Contamination Recall Scheme)

253. Plaintiff repeats and re-alleges each of the allegations set forth above as if fully set forth herein.

254. The Director Defendants all owed and owe fiduciary duties to J&J and its shareholders. By reason of their fiduciary relationships, Defendants specifically owed and owe J&J the highest obligation of good faith and loyalty in the administration of the affairs of the Company, including the oversight of J&J's compliance with federal laws governing the marketing of pharmaceuticals. Moreover, the Board had specific fiduciary duties as defined by the Company's key corporate governance documents and principles that, had they been discharged in accordance with the Board's obligations, would have necessarily prevented the misconduct and consequent harm to the Company alleged herein.

255. The Director Defendants consciously violated their corporate responsibilities in at least the following ways:

(a) Affirmatively and repeatedly declining to stop and prevent J&J's illegal marketing and promotion of off-label uses of Risperdal, Topamax, Natrecor and the Company's biliary stents after receiving reports of such illegal activity and numerous red flags indicating such widespread illegality, and/or consciously disregarding such reports and activity;

(b) Deciding not to act to stop and prevent J&J's illegal kickbacks to health care professionals and organizations for prescribing, recommending or using multiple J&J drugs and medical devices, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and/or consciously disregarding such reports and activity; and

(c) Approving and/or consciously disregarding J&J's business plan of marketing its drugs through the widespread illegal promotion of off-label uses and dosages and through illegal kickbacks to healthcare professionals in order to maximize J&J's short-term profit but at the expense of shareholder's long-term interests and J&J's reputation and goodwill.

256. As a direct and proximate result of the Director Defendants' conscious failure to perform their fiduciary obligations, the Company has sustained and will sustain significant damages, not only monetarily, but also to its corporate image and goodwill.

257. As a result of the misconduct alleged herein, the Director Defendants are liable to the Company.

COUNT II
(Against the Officer Defendants for Breach of Fiduciary Duty in connection with the Omnicare Kickback Scheme, the Risperdal Off-Label Promotion Scheme, the Natrecor Off-Label Promotion Scheme, the Topamax Off-Label Promotion Scheme, the DePuy Kickback Scheme, the Biliary Stent Off-Label Promotion Scheme, and the Delayed OTC Contamination Recall Scheme)

258. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

259. By reason of their positions as fiduciaries of the Company, the Officer Defendants owed duties of good faith, loyalty, and truthful disclosure. The Officer Defendants were all aware of and educated concerning the relevant laws and regulations concerning pharmaceutical and medical device marketing and were duty-bound to abide by the laws and regulations and to enforce compliance therewith.

260. The Officer Defendants consciously violated and breached these duties by causing J&J to employ a deliberate and systematic business plan of artificially increasing sales by engaging in unlawful sales and promotion practices by numerous J&J employees for a prolonged period of time in violation of FDA requirements, federal healthcare program requirements and/or the Federal anti-kickback statute.

261. The Officer Defendants authorized and implemented J&J policies and practices of encouraging the widespread illegal marketing and promotion of off-label uses of J&J drugs and medical devices, as well as the payment of illegal kickbacks to healthcare professionals and organizations to induce the prescription, recommendation and use of J&J drugs and devices.

262. As a direct and proximate result of the Officer Defendants' breaches of fiduciary duty, the Company has sustained, and will continue to sustain, substantial harm, including the damages set forth herein.

263. The Officer Defendants are liable to the Company as a result of the acts alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. Declaring that the current and former directors and officers named as defendants herein have breached their fiduciary duties as alleged herein;

B. Requiring the defendants to pay to the Company the amounts by which it has been damaged or will be damaged by reason of the conduct complained of herein;

C. Awarding Plaintiffs and their counsel reasonable attorneys' fees, expert fees and other reasonable costs and expenses; and

D. Granting such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

Dated: April 21, 2010

/s/ Lisa J. Rodriguez
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VERIFICATION

I, JEANNE M CALHOUN, attest and verify that:

1. I am a plaintiff in the shareholder's derivative action commenced by the filing of the Complaint attached hereto.

2. I currently own, and have continuously owned at the times relevant to the claims set forth in the Complaint, shares of the common stock of nominal defendant Johnson & Johnson.

3. The facts set forth in the attached Complaint are true and correct to the best of my knowledge, information and belief. .

Dated: April 21, 2010

Jeanne M Calhoun